
Commonwealth of Virginia Radiation Protection Regulatory Guide



Guidance for Self-Shielded Irradiators

ORH-720 D

**Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219
Phone (804) 864-8150**

EXECUTIVE SUMMARY

Virginia Regulatory Guides (**VAREGS**) are issued to describe and make available to the applicant or licensee, acceptable methods of implementing specific parts of **12VAC5-481 ‘Virginia Radiation Protection Regulations,’** to delineate techniques used by staff in evaluating past specific problems or postulated accidents, and to provide guidance to applicants or licensees. VAREGS are not substitutes for **12VAC5-481 ‘Virginia Radiation Protection Regulations’**; therefore, compliance with them is not required. Methods and solutions different from those set forth in this guide will be acceptable if they provide a basis for the Virginia Department of Health (VDH), Radioactive Materials Program, to determine if a radiation protection program meets the current rule and protects public health and safety.

Comments and suggestions for improvements in this VAREG are encouraged at all times and it will be revised, as appropriate, to accommodate comments and to reflect new information or experience. Comments should be sent to: **Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.**

Request for single copies of this guide (which may be reproduced) can be made in writing to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219. This guide is also available on our website:

<http://www.vdh.virginia.gov/radiological-health/radiological-health/materials/forms-postings/>.

This VAREG ‘Guidance for Self-Shielded Irradiators’ has been developed to streamline the application process for a Self-Shielded Irradiator License. A copy of the VDH Form, ‘Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators’ is located in **Appendix A** of this guide.

Appendix C through **Q** provides examples, models, procedures and additional information that can be used when completing the application.

It typically takes 60-90 days for a license to be processed and issued if the application is complete. When submitting the application be sure to include the appropriate application fee listed in **12VAC5-490.**

In summary, the applicant will need to do the following to submit an application for a Self-Shielded Irradiator license:

- Use this regulatory guide to prepare the VDH Form, ‘Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators’ (**Appendix A**).
- Complete the VDH Form, ‘Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators’ (**Appendix A**). See “Contents of Application” of the guide for additional information.
- Include any additional attachments.
 - All supplemental pages should be on 8 ½” x 11” paper.
 - Please identify all attachments with the applicant’s name and license number (if a renewal).
- Avoid submitting proprietary information unless it is absolutely necessary. If submitted, proprietary information and other sensitive information should be clearly identified and a request made to withhold from public disclosure.
- Submit an original signed application along with attachments (if any). This submission can be made via scanned copies forwarded via facsimile or electronic mail or via postal mail of the documents.
- Submit the application fee (for new licenses only).
- Retain one copy of the licensee application and attachments (if any) for your future reference. You will need this information because the license will require that radioactive material be possessed and used in accordance with statements, representation, and procedures provided in the application and supporting documentation.

If you have any questions about the application process, please contact this office at (804) 864-8150.

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ABBREVIATIONS

ALARA	as low as is reasonably achievable
ALI	annual limit on intake
ANSI	American National Standards Institute
AU	authorized user
bkg	background
Bq	Becquerel
CaF ₂	calcium fluoride
cc	centimeter cubed
CDE	committed dose equivalent
CEDE	committed effective dose equivalent
CFR	Code of Federal Regulations
Ci	Curie
CD-ROM	compact disc-read only memory
C/kg	coulomb/kilogram
cm ²	centimeter squared
Co-60	cobalt-60
cpm	counts per minute
Cs-137	cesium-137
d	Day
DOE	United States Department of Energy
DOT	United States Department of Transportation
dpm	disintegrations per minute
EDE	effective dose equivalent
FDA	United States Food and Drug Administration
ft	Foot
GBq	Gigabecquerel
G-M	Geiger-Mueller
GPO	Government Printing Office
hr	Hour
IN	Information Notice
IP	Inspection Procedure
kg	kilogram
LiF	lithium fluoride
m	meter
MBq	megabecquerel
mCi	millicurie
MeV	million electron volt
mGy	milligray
mo	Month
MOU	memorandum of understanding
mR	milliroentgen
mrem	millirem
mSv	millisievert
NCRP	National Council on Radiation Protection and Measurements
NIST	National Institute of Standards and Technology

NMSS	Office of Nuclear Material Safety and Safeguards
NRC	United States Nuclear Regulatory Commission
NTIS	National Technical Information Service
NVLAP	National Voluntary Laboratory Accreditation Program
OSL	optically stimulated luminescence dosimeters
OSP	Office of State Programs
P&GD	Policy and Guidance Directive
QA	quality assurance
R	roentgen
Rev.	revision
RG	Regulatory Guide
RQ	reportable quantities
RSO	radiation safety officer
SDE	shallow-dose equivalent
Sr-90	strontium-90
SFPO	Spent Fuel Project Office
SI	International System of Units (abbreviated SI from the French Le Systeme Internationale d'Unites)
SSD	sealed source and device
SSDR	Sealed Source and Device Registration
std	Standard
Sv	Sievert
TAR	technical assistance request
TBq	Terabecquerel
TEDE	total effective dose equivalent
TI	transportation index
TLD	thermoluminescent dosimeters
URL	uniform resource locator
U. S. C.	United States Code
USDA	United States Department of Agriculture
VAREG	Virginia Regulatory Guidance
VDH	Virginia Department of Health
wk	Week
yr	Year
μCi	microcurie
%	percent

PURPOSE OF GUIDE

This document provides guidance to an applicant preparing a license application for Self-Shielded Irradiator License. It also provides guidance on VDH's criteria for evaluating a Self-Shielded Irradiator license application. It is not intended to address the research and development or the commercial aspects of manufacturing, distribution, and service of self-shielded irradiators and their associated sources. Within this document, the phrases or terms, 'self-shielded irradiator', 'self-contained irradiators', or 'irradiators' are used interchangeably.

Note: Irradiators subject to the requirements of 12VAC5-481 'Virginia Radiation Protection Regulations' Part XII, 'Radiation Safety Requirements for Irradiators' are not discussed in this guide.

Irradiators are used for a variety of purposes in research, industry, and other fields resulting in different types for specific uses. Typical uses are:

- Irradiating blood or blood products
- Sterilizing or reducing microbes in medical and pharmaceutical supplies
- Preserving foodstuffs
- Studying radiation effects
- Synthesizing and modifying chemicals and polymers
- Eradicating insects through sterile male release programs
- Calibrating thermoluminescent dosimeters (TLDs).

The American National Standards Institute (ANSI) has developed and published safety standards for gamma irradiators. In determining basic safety requirements, ANSI divided all gamma irradiators into four general categories. This report deals with the type of irradiator discussed in ANSI Standard N433.1, "*Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiators (Category I)*".

Note: Copies of this standard may be ordered electronically at <http://www.ansi.org> or by writing to ANSI, 1430 Broadway, New York, NY 10018. Copies are also available from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161 (1-800-533-6847).

This guide also uses the same definition of a self-shielded irradiator as the ANSI definition for a Category I irradiator: "*[a]n irradiator in which the sealed source(s) is completely contained in a dry container constructed of solid materials, the sealed source(s) is shielded at all times, and*

human access to the sealed source(s) and the volume(s) undergoing irradiation is not physically possible in its designed configuration."

Depending on the design, the radiation source within the irradiator may be in a fixed position or may be movable. In the latter case, interlocks are used to ensure that the source does not move into a position that, during normal use of the irradiators, may cause a radiation hazard to any individual. Bypassing or failure of an interlock could cause persons to be exposed to high levels of radiation.

Self-shielded irradiators typically contain several hundred to several thousand terabecquerels (TBq) (or curies (Ci)) of cesium-137 (Cs-137) or cobalt-60 (Co-60) and range in weight from several hundred to several thousand kilograms (kg) (or pounds). Other irradiators contain megabecquerel (MBq) (or millicurie (mCi)) quantities of strontium-90 (Sr-90), a beta emitter, and are used primarily for thermoluminescent dosimeter (TLD) calibration.

This guide identifies the information needed to complete VDH Form, 'Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators.' (**Appendix A**).

The format for each item in this guide is as follows:

- **Rule** - references **12VAC5-481 'Virginia Radiation Protection Regulations'** requirements applicable to the item;
- **Criteria** - outlines the criteria used to judge the adequacy of the applicant's response;
- **Discussion** - provides additional information on the topic sufficient to meet the needs of most readers.

The information submitted in the application must be sufficient to demonstrate that proposed equipment, facilities, personnel, and procedures are adequate to protect the health and safety of the citizens of the Commonwealth of Virginia in accordance with agency guidelines.

Submission of incomplete or inadequate information will result in delays in the approval process for the license. Additional information will be requested when necessary to ensure that an adequate radiation safety program has been established. Such requests for additional information will delay completion of the application's review and may be avoided by a thorough study of the rule and these instructions prior to submitting the application.

12VAC5-481 ‘Virginia Radiation Protection Regulations’ requires the applicant and/or licensee to develop, document, and implement procedures that will ensure compliance with the rule. The appendices describe radiation protection procedures. Each applicant should read the rule and procedures carefully and then decide if the procedure addresses specific radiation protection program needs at the applicant’s facility. Applicants may adopt a procedure included in this VAREG or they may develop their own procedures to comply with the applicable rule.

In this guide, “dose” or “radiation dose” means absorbed dose, dose equivalent, effective dose equivalent, committed dose equivalent, committed effective dose equivalent, or total effective dose equivalent (TEDE). These terms are defined in **12VAC5-481-10**. Rem and Sievert (Sv), its SI equivalent (1 rem = 0.01 Sv), are used to describe units of radiation exposure or dose. These units are used because **12VAC5-481 ‘Virginia Radiation Protection Regulations’, Part IV ‘Standards for Protection Against Radiation’** sets dose limits in terms of rem, not rad or roentgen. Furthermore, radioactive materials commonly used in medicine emit beta and photon radiation, for which the quality factor is 1; a useful rule of thumb is an exposure of 1 roentgen is equivalent to an absorbed dose of 1 rad and dose equivalent of 1 rem.

This VAREG provides the latest guidance, shows the requirements in terms of the **12VAC5-481 ‘Virginia Radiation Protection Regulations’**, and provides a user-friendly format to assist with the preparation of a license application.

LICENSES

Applicants should study this document, related guidance, and all applicable regulations carefully before completing the VDH Form, ‘Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators’. VDH expects licensees to provide requested information on specific aspects of their proposed radiation protection program in attachments to the application. When necessary, VDH may ask the applicant for additional information to gain reasonable assurance that an adequate radiation protection program has been established.

After a license is issued, the licensee must conduct its program in accordance with the following:

- Statements, representations, and procedures contained in the application and in correspondence with VDH;
- Terms and conditions of the license; and
- **12VAC5-481 ‘Virginia Radiation Protection Regulations’.**

THE ‘AS LOW AS IS REASONABLY ACHIEVABLE (ALARA)’ CONCEPT

12VAC5-481-630, Radiation protection programs, states that “*each licensee shall develop, document, and implement a radiation protection program commensurate with the scope and extent of licensed activities*” and “*the licensee shall use, to the extent practical, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are...ALARA.*” This section also requires that licensees review the content of the radiation protection program and its implementation annually.

Information directly related to radiation protection standards in **12VAC5-481 ‘Virginia Radiation Protection Regulations’, Part IV, ‘Standards for Protection Against Radiation’**, is contained in:

- NRC’s NUREG-1736, ‘Consolidated Guidance: 10 CFR Part 20 - Standards for Protection Against Radiation’.

Applicants should consider the ALARA philosophy detailed in these reports when developing plans to work with licensed radioactive materials.

WHO REGULATES AT FACILITIES IN THE COMMONWEALTH OF VIRGINIA?

In the special situation of work at federally controlled sites in the Commonwealth of Virginia, it is necessary to know the jurisdictional status of the land to determine whether Nuclear Regulatory Commission (NRC) or VDH has regulatory authority. The NRC has regulatory authority over land determined to be under “exclusive federal jurisdiction,” while VDH has jurisdiction over non-exclusive federal jurisdiction land (see **Table 1**). Applicants and licensees are responsible for finding out, in advance, the jurisdictional status of the specific areas where they plan to conduct licensed operations. VDH recommends that applicants and licensees ask their local contacts for the federal agency controlling the site (e.g., contract officer, base environmental health officer, district office staff) to help determine the jurisdictional status of the land and to provide the information in writing, so that licensees can comply with NRC or VDH regulatory requirements, as appropriate. The following table lists examples of regulatory authority.

Table 1: Who Regulates the Activity?

Applicant and Proposed Location of Work	Regulatory Agency
Federal agency regardless of location (except that Department of Energy [DOE] and, under most circumstances, its prime contractors are exempt from licensing [10 CFR 30.12])	NRC
Non-federal entity in non-Agreement State, U.S. territory, or possession	NRC
Non-federal entity in VA at non-federally controlled site	VDH
Non-federal entity in VA at federally-controlled site not subject to exclusive Federal jurisdiction	VDH
Non-federal entity in VA at federally-controlled site subject to exclusive federal jurisdiction	NRC

A current list of Agreement States (states that have entered into agreements with the NRC that give them the authority to license and inspect radioactive material used or possessed within their borders), including names, addresses, and telephone numbers of responsible officials are maintained by the NRC Office of Federal and State Materials and Environmental Management Programs and is available on their website: <http://nrc-stp.ornl.gov/>.

MANAGEMENT RESPONSIBILITY

VDH endorses the philosophy that effective radiation protection program management is vital to safe operations that comply with VDH regulatory requirements.

'Management' refers to the chief executive officer or other individual having the authority to manage, direct, or administer the licensee's activities or that person's delegate or delegates.

To ensure adequate management involvement, a management representative (i.e., chief executive officer or delegate) must sign the submitted application acknowledging management's commitments to and responsibility for all the following:

- Radiation protection, security, and control of radioactive materials, and compliance with rule;
- Knowledge about the contents of the license and application;
- Compliance with current VDH and United States Department of Transportation (DOT) regulations and the licensee's operating and emergency procedures;
- Provision of adequate resources (including space, equipment, personnel, time and, if needed, contractors) to the radiation protection program to ensure that public, and workers are protected from radiation hazards;
- Appointment of a qualified individual who has agreed in writing to work as the RSO;

Management may delegate individuals (i.e., an RSO or other designated individual) to submit amendment requests to VDH. A correspondence delegation letter must be completed, signed by management and submitted to VDH. A sample letter has been included in **Appendix C**.

SAFETY CULTURE

Nuclear safety culture is defined as the core values and behaviors resulting from a collective commitment by leaders and individuals to emphasize safety over competing goals to ensure protection of people and the environment. Individuals and organizations performing regulated activities bear the primary responsibility for safely handling and securing these materials. Experience has shown that certain personal and organizational traits are present in a positive safety culture. A trait, in this case, is a pattern of thinking, feeling, and behaving that emphasizes safety, particularly in goal conflict situations (e.g., production versus safety, schedule versus safety, and cost of the effort versus safety). **Table 2** show traits of a positive nuclear safety culture.

Table 2: Traits of a Positive Nuclear Safety Culture

Trait	Result
Leadership: Safety Values and Actions	Leaders demonstrate a commitment to safety in their decisions and behaviors
Problem Identification and Resolution	Issues potentially impacting safety are promptly identified, fully evaluated, and promptly addressed and corrected commensurate with their significance
Personal Accountability	All individuals take personal responsibility for safety
Evaluating Work Processes	The process of planning and controlling work activities is implemented so that safety is maintained
Continuous Learning	Opportunities to learn about ways to ensure safety are sought out and implemented
Environment for Raising Concerns	A safety conscious work environment is maintained where personnel feel free to raise safety concerns without fear of retaliation, intimidation, harassment, or discrimination
Effective Safety Communications	Communications maintain a focus on safety
Respectful Work Environment	Trust and respect permeate the organization
Questioning Attitude	Individuals avoid complacency and continually challenge existing conditions and activities in order to identify discrepancies that might result in error or inappropriate action

Individuals and organizations performing regulated activities are expected to establish and maintain a positive safety culture commensurate with the safety and security significance of their activities and the nature and complexity of their organizations and functions. This applies to all licensees, holders of quality assurance programs approvals, vendors, and suppliers of safety-related components, and applicants for a license or quality assurance program approval, subject to VDH authority. More information related to safety culture can be found at <http://www.nrc.gov/about-nrc/regulatory/enforcement/safety-culture.html>

APPLICABLE RULE

It is the applicant's or licensee's responsibility to obtain, read and follow **12VAC5-481, 'Virginia Radiation Protection Regulations'**.

The following parts of **12VAC5-481, 'Virginia Radiation Protection Regulations'** contain requirements applicable to Self-Shielded Irradiators licensees:

- Part I: 'General Provisions'
- Part III: 'Licensing of Radioactive Material'
- Part IV: 'Standards for Protection Against Radiation'
- Part X: 'Notices, Instructions and Reports to Workers; Inspections'
- Part XIII: 'Transportation of Radioactive Material'

Request for single copies of the above documents (which may be reproduced) can be made in writing to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219 or, for an electronic copy, go to our web site at:

<http://www.vdh.virginia.gov/radiological-health/radiological-health/materials/12vac5-481-virginia-radiation-protection-regulations/>.

HOW TO FILE

Applicants for a materials license should do the following:

- Be sure to use the current guidance from VDH in preparing an application.
- Complete VDH Form, ‘Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators’ (**Appendix A**).
- For each separate sheet, other than submitted with the application, identify and key it to the item number on the application, or the topic to which it refers.
- Submit all documents on 8 ½ x 11 inch paper.
- Avoid submitting proprietary information unless it is absolutely necessary. If submitted, proprietary information and other sensitive information should be clearly identified and a request made to withhold from public disclosure.
- Submit an original, signed application. This submission can be made via scanned copies forwarded via facsimile or electronic mail or via postal mail of the documents.
- Retain one copy of the license application for your future reference.

Deviations from the suggested wording of responses as shown in this VAREG or submission of alternative procedures will require a more detailed review.

Note: Personal employee information (i.e., home address, home telephone number, Social Security Number, date of birth, and radiation dose information) should not be submitted unless specifically requested by the agency.

WHERE TO FILE

Applicants wishing to possess or use radioactive material in Commonwealth of Virginia are subject to the requirements of **12VAC5-481 ‘Virginia Radiation Protection Regulations’** and must file a license application with:

**Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, Virginia 23219**

LICENSE FEES

The appropriate fee must accompany each application. Refer to **12VAC5-490** to determine the amount of the fee. VDH will not issue the new license prior to fee receipt. Once the technical review has begun, no fees will be refunded. Application fees will be charged regardless of VDH's disposition of an application or the withdrawal of an application.

Licensees are also subject to annual fees; refer to **12VAC5-490**.

Direct all questions about VDH's fees or completion of **Item 11** of VDH Form, 'Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators' (**Appendix A**) to: Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, Virginia 23219 or (804) 864-8150.

CONTENTS OF APPLICATION

Item 1: Type of Application

Obtain the correct application form for either a new license or a renewal, check the appropriate box and, if appropriate, list the license number for a renewal.

This guide is written to instruct a new licensee in the process of applying for a radioactive material license. Not all discussions will be appropriate to a licensee renewing an existing license.

Item 2: Name and Mailing Address of Applicant

List the legal name of the applicant's corporation or other legal entity with direct control over use of the radioactive material; a division or department within a legal entity may not be a licensee. An individual may be designated as the applicant only if the individual is acting in a private capacity and the use of the radioactive material is not connected with employment in a corporation or other legal entity. Provide the mailing address where correspondence should be sent. **A Post Office box number is an acceptable mailing address.**

Notify the agency of changes in mailing address.

The licensee must also provide sufficient information for the agency to ensure the proposed corporation or controlling legal entity is a valid entity. Verification of this identity can be accomplished by submitting a copy of the company's license from the NRC or another Agreement State or a government contract or certification, etc.

Note: The agency must be notified before control of the license is transferred or when bankruptcy proceedings; see below for more details.

Timely Notification of Transfer of Control

Rule: 12VAC5-481-330, 12VAC5-481-450, 12VAC5-481-500

Criteria: Licensees must provide full information and obtain the VDH's **prior written consent** before transferring control of the license, or, as some licensees call it, 'transferring the license'.

Discussion: Transferring control may be the result of mergers, buyouts, or majority stock transfers. Although it is not the VDH's intent to interfere with the business decisions of licensees, it is necessary for licensees to obtain prior agency written consent before the transaction is finalized. This is to ensure the following:

- Radioactive materials are possessed, used, or controlled only by persons who have valid VDH, NRC, or another Agreement State licenses;
- Materials are properly handled and secured;
- Persons using these materials are competent and committed to implementing appropriate radiological controls;
- A clear chain of custody is established to identify who is responsible for final disposition of records and licensed material; and
- Public health and safety are not compromised by the use of such materials.

Appendix D identifies the information to be provided about changes of ownership or control.

Notification of Bankruptcy Proceedings

Rule: 12VAC5-481-500

Criteria: **12VAC5-481-500** states: “*Each licensee shall notify the agency in writing immediately following the filing of a voluntary or involuntary petition for bankruptcy under any Chapter of Title 11 (Bankruptcy) of the United States Code by or against: 1. The licensee 2. An entity (as that term is defined in 11 USC §101 (15)) controlling the licensee or listing the license or licensee as property of the estate; or 3. An affiliate (as that term is defined in 11 USC §101 (2)) of the licensee*” and “*...shall indicate the bankruptcy court in which the petition for bankruptcy was filed and the date of filing of the petition*”.

Discussion: Even though a licensee may have filed for bankruptcy, the licensee remains responsible for all regulatory requirements. VDH needs to know when licensees are in bankruptcy proceedings in order to determine whether all licensed materials are accounted for and adequately controlled and whether there are any public health and safety concerns (e.g., contaminated facility). VDH shares the results of its determinations with other involved entities (e.g., trustee) so that health and safety issues can be resolved before bankruptcy actions are completed.

Licensee must notify VDH immediately of the filing of a bankruptcy petition.

Item 3: Person to Be Contacted Regarding Application

Criteria: Identify the individual who can answer questions about the application and include his or her telephone number.

Discussion: This is typically the proposed RSO, unless the applicant has named a different person as the contact. The agency will contact this individual if there are questions about the application.

Notify the agency if the contact person or his or her telephone number changes so that the agency can contact the applicant or licensee in the future with questions, concerns, or information. This notice is ‘for information only’ and does not require a license amendment.

Item 4: Address(es) Where Licensed Material Will Be Used or Possessed

Rule: 12VAC5-481-450, 12VAC5-481-500

Criteria: Applicants must provide a specific address for each location where radioactive material will be used, stored, or dispatched.

Discussion: Specify the street address, city, and state or other descriptive address (e.g., on Highway 58, 5 miles east of the intersection of Highway 58 and State Route 19, Anytown, VA, Zip) for each facility. The descriptive address should be sufficient to allow a VDH inspector to find the facility location. **A Post Office Box address is not acceptable.**

A VDH approved license amendment is required before locating an irradiator at an address not already listed on the license or at a new room location, whether that irradiator is an additional unit or a relocation of an existing unit.

Being granted a VDH license does not relieve a licensee from complying with other applicable federal, state, or local regulations (e.g., local zoning requirements; a local ordinance requiring registration of a radiation-producing device).

Note: As discussed later under ‘Financial Assurance and Record Keeping for Decommissioning’, licensees do need to maintain permanent records on where licensed material was used or stored while the license was in force. This is important for making future determinations about the release of these locations for unrestricted use (e.g., before the license is terminated). For self-shielded irradiator licensees, acceptable records are sketches or written descriptions of the specific locations where each irradiator is used or stored and any information relevant to damaged devices or leaking radioactive sources.

Item 5: Radiation Safety Officer (RSO)

Rule: 12VAC5-481-450, 12VAC5-481-451, 12VAC5-481-630

Criteria: A Radiation Safety Officer (RSO) must have adequate training and experience. Successful completion of training as described in **Appendix G** is evidence of adequate training and experience.

Discussion: The person responsible for the radiation protection program is called the RSO. The RSO needs independent authority to stop operations that he or she considers unsafe. He or she must have sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radioactive materials are used in a safe manner. Typical RSO duties are provided in **Table 3** and described in **Appendix H**. VDH requires the name of the RSO on the license to ensure that licensee management has always identified a responsible, qualified person and that the named individual knows of his or her designation as RSO.

Table 3. RSO Duties and Authorities

Radiation Safety Officer Duties and Authorities
1. Establish and oversee all operating, emergency, and ALARA procedures and review them regularly.
2. Oversee all material disposals for compliance with VDH/DOT rules.
3. Ensure required inventories, leak tests, etc are conducted and the records are recorded and maintained.
4. Ensure irradiator security is maintained.
5. Operations are conducted safely and corrective actions are implemented, when necessary, including terminating operations.
6. Oversee training program for authorized users.
7. Ensure radiation levels are ALARA and personnel monitoring devices are used if required.
8. Maintain documentation to demonstrate compliance with the dose to the individual member of public.

9. Make certain all required routine maintenance is performed and operations and equipment are used properly.
10. Perform annual audit and notify appropriate parties if any item is found to be not in compliance with VDH rule.
Above all, the RSO is the key to maintaining the radiation safety of the operations to the workers, the public, and the environment.

Note: It is important to notify the agency as soon as possible, of changes in the designation of the RSO. Alternative responses will be evaluated using the criteria listed above.

Item 6: Authorized Users

Rule: 12VAC5-481-450, 12VAC5-481-451, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-1100, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2310

Criteria: Authorized users (AUs) must have adequate training and experience. Successful completion of training as described in **Appendix G** is evidence of adequate training and experience.

Discussion: An AU is a person whose training and experience meet VDH criteria, who is named either explicitly or implicitly on the license, and who uses or directly supervises the use of licensed material. AUs must ensure the proper use, security, and routine maintenance of self-shielded irradiators containing licensed material. They must have appropriate training to provide reasonable assurance that they will use the irradiator safely, maintain security of and access to the irradiator, and respond appropriately to accidents and malfunctions.

An AU is considered to be supervising the use of licensed material when he or she directs personnel in operations involving the material. Although the AU may delegate specific tasks to supervised users (e.g., maintaining records), he or she is still responsible for safe use of licensed material.

Item 6.1: Training for Individuals Working in or Frequenting Restricted Areas (Instructions to Occupationally Exposed Workers and Ancillary Personnel)

Rule: 12VAC5-481-450, 12VAC5-481-451, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2260, 12VAC5-481-2270, 12VAC5-481-2280, 12VAC5-481-2310

Criteria: Individuals working with, as well as in the vicinity of, a self-shielded irradiator must have adequate training and experience. For those individuals who are not AUs yet work in the vicinity of a self-shielded irradiator and, in the course of employment, are likely to receive in a year an occupational dose of radiation over 1 millisievert (mSv) (100 millirem (mrem)), the licensee must provide training as required by **12VAC5-481-2270**. The extent of this training must be commensurate with potential radiological health protection problems present in the work place.

Discussion: Individuals, other than AUs (e.g., biomedical engineers), may perform routine maintenance on irradiators. However, they must be trained in radiation safety and in the irradiator manufacturers' operating procedures, or they must work under the supervision and in the direct physical presence of someone who has this training.

Some licensees may have specific individuals trained to perform installations, relocations, non-routine maintenance, or repairs. Authorizations for these functions are separate from those for an AU or an individual who performs routine maintenance and will be specifically stated in a license condition. **Appendix I** contains training for individuals who will conduct non-routine maintenance.

A licensee may recognize that some individuals (e.g., housekeeping staff), although not likely to receive doses over 1 mSv (100 mrem), should receive training to ensure adequate security and control of licensed material. Licensees may provide these individuals with training commensurate with their involvement with licensed material. For example, housekeeping staff may receive training on the nature and location of the irradiator and the meaning of the radiation symbol, and instructions not to touch the irradiator and to remain out of the room if the irradiator door is open.

Item 7: Radioactive Material

Sealed Radioactive Material

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-451, 12VAC5-481-500

Criteria: Applicants must provide the manufacturer's (or distributor's) name and model number for each requested sealed source and device. Licensees will be authorized to possess and use only those sealed sources and devices specifically approved or registered by NRC or another Agreement State.

Discussion: A maximum possession limit, per isotope, is required to be requested; this should reflect the total number of sealed sources and devices containing a particular isotope (i.e., Cobalt-60) that would ever be possessed at any one time, including inactive sources being held for storage and devices awaiting shipment. This should also include sources and devices expected to be purchased at in the future. This limit is isotope specific (i.e., one limit for Cobalt-60 and another for Cesium-137) and not allowed to be exceeded; that is, the total of all sources and devices in the licensee's possession cannot exceed this limit. An amendment request must be made and an amended license received prior to obtaining more sources and devices.

Possession limits can be obtained from information provided by the manufacturer; specifically, the activity provided by the manufacturer on the sources and devices the licensee anticipates acquiring. This information will list each isotope with the activity for the source and device. A simple calculation can be performed with this information by totaling the number of each source and device, per isotope, that the licensee expects to possess at any one time. For example; a licensee anticipates possessing three shielded irradiators; two containing Cobalt-60 and 1 containing Cesium-137. The manufacturer states that each gauge has a maximum quality of 20 Ci of Cobalt-60 and 50 Ci of Cesium-137. The licensee is able to perform the simple calculation (20 multiplied by 2 and 50 multiplied by 1) to request a 40 Ci maximum possession limit for Cobalt-60 and a 50 Ci maximum possession limit of Cesium-137.

Licensees are also required to maintain a limit per device. This is separate from the maximum possession limit; this limit is applied to each source and device itself and is typically determined by the manufacturer's Sealed Source and Device Registration Certificate.

NRC or other Agreement States perform a safety evaluation of self-shielded irradiators before authorizing a manufacturer (or distributor) to distribute the irradiators to specific licensees. The safety evaluation is documented in a Sealed Source and Device Registration (SSDR) Certificate. Before the formalization of the SSDR process, some older irradiators may have been specifically approved on a license. Licensees can continue to use those units specifically listed on their licenses. Applicants must provide the manufacturer's (or distributor's) name and model number for each requested sealed source and device so that the agency can verify that they have been evaluated in an SSDR Certificate or specifically approved on a license.

As explained in an "*Urgent Notice*" with an enclosed Order, both dated July 3, 1984 (see **Appendix E**), an NRC licensee identified a malfunction that could have resulted in a radiation overexposure. The malfunction involved an interlock mechanism that would have failed to prevent a shielded door from being opened after the source had moved out of the shielded position. The Order, which remains in effect, modifies licenses that authorize J. L. Shepherd Mark I or Model 81-22 irradiators. Applicants wishing to use either of these models must comply with the Order's requirements.

Consult with the proposed manufacturer (or distributor) to ensure that requested sources and devices are compatible and conform to the sealed source and device designations registered with the NRC or another Agreement State. Licensees may not make any changes to the sealed source, device, or source/device combination that would alter the description or specifications from those indicated in the respective registration certificates, without obtaining VDH's prior permission in a license amendment. Such changes may necessitate a custom registration review to be conducted by NRC or another Agreement State; increasing the time needed to process a licensing action.

SSDR Certificates contain sections on "*Conditions of Normal Use*" and "*Limitation and Other Considerations of Use*". These sections may include limitations derived from conditions imposed by the manufacturer (or distributor), by particular conditions of use that would reduce radiation safety of the device, or by circumstances unique to the sealed source or device. For example, working life of the device or appropriate temperature and other environmental conditions may be specified. Except as specifically approved by VDH, licensees are required to use irradiators according to their respective SSDR Certificates. Applicants should obtain a copy of the certificate and review it with the manufacturer, distributor, or with the agency, to ensure that they understand and comply with the requirements of the SSDR.

Note: If necessary and manufacturer cannot supply the certificate, SSDR certificates are also available by calling the agency at (804) 864-8150.

Purpose(s) for Which Licensed Material Will Be Used

Rule: 12VAC5-481-440, 12VAC5-481-450, 12VAC5-481-500

Criteria: Proposed activity is authorized by **12VAC5-481 'Virginia Radiation Protection Regulations'**, and irradiators will be used only for the purposes for which they were designed and according to the manufacturer's (or distributor's) recommendations and instructions for use

as specified in an approved SDDR Certificate. Uses other than those already listed must not compromise the integrity of the source or source shielding or other components of the device critical to radiation safety.

Discussion: Allowed uses normally include irradiation of blood, insects, animals, biological samples, and inanimate objects. Usually prohibited are irradiation of flammable and explosive materials which may harm the shielding or the sealed source containment, or other materials (e.g., unsealed containers of acids or corrosive liquids) which may interfere with the safe operation of the device. Irradiation of food for commercial distribution to the public is subject to regulations of the Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA) and will not be discussed in this document.

Requests to irradiate items not listed or prohibited in the SDDR Certificate will be reviewed on a case-by-case basis. Applicants need to submit enough information to demonstrate that irradiation of the proposed items will not compromise the integrity of the source or source shielding, or other components critical to radiation safety of the device. Contact the agency for additional case-specific guidance. Being granted a VDH license does not relieve a licensee from complying with other applicable federal, state, or local regulations (e.g., FDA and USDA regulations about irradiation of food for commercial distribution).

Note: For more information about the SDDR process, see the current version of NUREG - 1556, Vol. 3, "*Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration*". It can be accessed at NRC's web site, <http://www.nrc.gov>.

Item 7.1 Financial Assurance and Recordkeeping for Decommissioning

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: A licensee authorized to possess licensed material in excess of the limits specified in **12VAC5-481-450 C** must meet the requirements for decommissioning financial assurance.

All licensees are required to maintain, in an identified location, records of information important to decommissioning of the facility until the site, or any area, is released for unrestricted use. Licensees must transfer records important to decommissioning either to the new licensee before licensed activities are transferred or assigned in accordance with **12VAC5-481-500** or to VDH before the license is terminated.

Discussion: VDH wants to ensure that decommissioning will be carried out with minimum impact on public and occupational health and safety and the environment. There are two parts to the rule: financial assurance that applies to SOME licensees, and recordkeeping that applies to ALL licensees.

The requirements for financial assurance are specific to the types and quantities of radioactive material authorized on a license. Most self-shielded irradiator applicants and licensees do not need to take any action to comply with the financial assurance requirements because their total inventory of licensed material does not exceed the limits in **12VAC5-481-450 C**. The limits for typical self-shielded irradiator sealed sources are shown in **Table 4**. Applicants requesting more than one radionuclide need to use the sum of the ratios method to determine whether financial assurance is needed. See **Appendix F** for additional information.

Table 4. Minimum Inventory Quantity Requiring Financial Assurance

Radionuclide	Activity	
	Gigabecquerel (GBq)	Curie (Ci)
Cs-137	3.7×10^6	100,000
Co-60	3.7×10^5	10,000
Sr-90	3.7×10^4	1,000

Applicants and licensees wanting to possess self-shielded irradiators or irradiators and other licensed materials exceeding the limits in **12VAC5-481-450 C** must submit evidence of financial assurance or a decommissioning funding plan (**12VAC5-481-450 C**). NRC Regulatory Guide 3.66, "*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72*", contains approved wording for each mechanism authorized by the regulation to guarantee or secure funds except for the Statement of Intent for government licensees. See **Appendix F** for the recommended wording for a Statement of Intent.

VDH will authorize possession exceeding the limits shown in **Table 4**, without requiring decommissioning financial assurance, for the purpose of normal source exchange for no more than 30 days.

The same regulation also requires that licensees maintain records important to decommissioning in an identified location. All portable gauge licensees need to maintain records of structures and equipment where gauges are used or stored at locations specifically listed on the license. As-built drawings with modifications of structures and equipment shown as appropriate fulfill this requirement. If drawings are not available, licensees may substitute appropriate records concerning the areas and locations. In addition, if portable gauge licensees have experienced unusual occurrences (e.g., leaking sources, other incidents that involve spread of contamination), they also need to maintain records about contamination that remains after cleanup or that may have spread to inaccessible areas.

For self-shielded irradiator licensees whose sources have never leaked, acceptable records important to decommissioning are sketches or written descriptions of the specific locations where each irradiator was used or stored.

References: To obtain copies of RG 3.66 and P&GD FC 90-2 (Rev. 1), "*Standard Review Plan for Evaluating Compliance with Decommissioning Requirements*", dated April 30, 1991 are available at NRC's web site, <http://www.nrc.gov>.

Item 8: Facilities and Equipment

Rule: 12VAC5-481-450, 12VAC5-481-451, 12VAC5-481-590, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-850, 12VAC5-481-860, 12VAC5-481-880

Criteria: Facilities and equipment must be adequate to protect health and minimize danger to life or property.

Discussion: Self-shielded irradiators incorporate many engineering features to protect individuals from unnecessary radiation exposure. These devices are usually designed for use in a laboratory environment (i.e., inside a building protected from the weather and without wide variations of temperature and humidity). For information to help applicants determine the location of irradiators, see the sections on the SSDR Certificate entitled, "*Conditions of Normal Use*" and "*Limitations and/or Other Considerations of Use*".

For example, if a proposed location for a self-shielded irradiator is not within the conditions of normal use or the limitations of use, the applicant will need to provide adequate justification. In addition, the applicant will need to take compensatory measures (e.g., increased surveillance and maintenance) to ensure that the irradiator operates as designed and provides the intended level of protection. NRC IN 96-35, "*Failure of Safety Systems on Self-Shielded Irradiators Because of Inadequate Maintenance and Training*", dated June 11, 1996, discusses an incident resulting from irradiator failure in which the lack of a climate-controlled environment (i.e., loading dock) may have accelerated the degradation of internal components leading to a failed interlock and excessive dose received by an irradiator operator.

Self-shielded irradiators vary in weight from several hundred to several thousand kilograms (pounds). Before installing an irradiator, licensees need to evaluate whether the floor in the proposed location can support the irradiator. Often licensees locate self-shielded irradiators on a ground floor. Some smaller and lighter irradiators require additional security measures to prevent unauthorized removal (e.g., locked in a room, bolted to the floor). For more information see **Item 9.6** 'Operating and Emergency Procedures' and **Item 9.5** 'Public Dose'.

The fire-resistant properties of most irradiators should provide adequate radioactive material containment and shielding integrity in most situations; however, additional protection is desirable for some situations. For example, the room housing the irradiator should be equipped with an automatically operated fire detection and control system (sprinkler, chemical, or gas). As an alternative, the self-shielded irradiator should be located under conditions (e.g., ground floor location in fire-resistant building with little combustible material) and other controls (e.g., coordination with and training of firefighting personnel) that ensure a low level of radiation risk attributable to fires.

The applicant should identify the self-shielded irradiator location by room number and should submit drawings of the location within the facility.

Provide the following on the facility diagrams:

- Drawings should be to scale, and indicate the scale used;
- Location, room numbers, and principal use of each room or area where radioactive material is used or stored;

- Location, room numbers, and principal use of each adjacent room (e.g., office, file, toilet, closet, hallway), including areas above, beside, and below; and,
- If multiple locations of storage, indicate address on diagram.

References: NRC INs are available at NRC's web site, <http://www.nrc.gov>.

Item 9: Radiation Safety Program

Item 9.1: Audit Program

Rule: 12VAC5-481-450, 12VAC5-481-451, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-990

Criteria: Licensees must review the content and implementation of their radiation protection programs annually to ensure the following:

- Compliance with VDH and DOT regulations (as applicable), and the terms and conditions of the license;
- Occupational doses and doses to members of the public are as low as is reasonably achievable (ALARA) (**12VAC5-481-630**); and
- Records of audits and other reviews of program content are maintained for 3 years.

Discussion: **Appendix J** contains a suggested audit program that is specific to the use of self-shielded irradiators and is acceptable to the agency. All areas indicated in **Appendix J** may not be applicable to every licensee and may not need to be addressed during each audit. For example, licensees do not need to address areas that do not apply to their activities or activities which have not occurred since the last audit.

Currently, the agency's emphasis in inspections is to perform actual observations of work in progress. As a part of their audit programs, applicants should consider performing unannounced audits of irradiator users to determine if, for example, operating and emergency procedures are available and are being followed.

It is essential that once identified, problems be corrected comprehensively and in a timely manner; NRC IN 96-28, *"Suggested Guidance Relating to Development and Implementation of Corrective Action"*, dated May 1, 1996, provides guidance on this subject. The agency will review the licensee's audit results and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. If violations are identified by the licensee and these steps are taken, the agency can exercise discretion and may elect not to cite a violation. The agency's goal is to encourage prompt identification and prompt, comprehensive correction of violations and deficiencies.

With regard to audit records, **12VAC5-481-990** requires licensees to maintain records of audits and other reviews of program content and implementation.. The agency will find that audit records containing the following information to be acceptable: date of audit, name of person(s) who conducted audit, persons contacted by the auditor(s), areas audited, audit findings, corrective actions, and follow-up.

Item 9.2: Radiation Monitoring Instruments

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-1000

Criteria: Licensees must possess, or have access to, radiation monitoring instruments that are necessary to protect health and minimize danger to life or property. Instruments used for quantitative radiation measurements must be calibrated at intervals not to exceed 12 months for the radiation measured.

Discussion: All licensees possessing self-shielded irradiators should have, or have access to, calibrated radiation detection instruments to determine radiation levels in areas adjacent to the irradiator. Usually, it is not necessary for a licensee to have a survey meter solely for use during irradiator operations, since it is not expected that a survey be performed each time a sample is irradiated. In these cases it is acceptable for the meter to be available on short notice in the event of an accident or malfunction that could reduce the shielding of the sealed source(s). Surveys may be required to verify source integrity and to ensure that dose rates in unrestricted areas and public and occupational doses are within regulatory limits.

As explained in an "*Urgent Notice*" with an enclosed Order, both dated July 3, 1984 (see **Appendix E**), an NRC licensee identified a malfunction that could have resulted in a radiation overexposure. The malfunction involved an interlock mechanism that would have failed to prevent a shielded door from being opened after the source had moved out of the shielded position. The Order, which remains in effect, modifies licenses which authorize J. L. Shepherd Mark I or Model 81-22 irradiators and requires licensee to provide either a calibrated and operable radiation survey meter or room monitor for use with either of these irradiators. Although not required for all licensees possessing moving-source irradiators, it would be prudent for these licensees to use either a calibrated survey meter or room monitor to ensure that the sources are in the shielded position whenever a sample is not undergoing irradiation.

The agency requires that survey meter calibrations be performed by the instrument manufacturer or a person specifically authorized by VDH, the NRC or another Agreement State, unless the applicant specifically requests this authorization. Applicants seeking authorization to perform survey meter calibrations must follow the survey instrument calibration program in **Appendix K** or submit alternative procedures for review.

Notes:

- Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will be conditioned to require compliance with the terms of the Order in **Appendix E**. Applicants requesting these irradiators must ensure that their radiation detection instruments meet these requirements.
- Applicants who plan to perform non-routine maintenance that will affect safety-critical components (e.g., sealed source, radiation shielding, source movement control or mechanism, interlocks) will need to possess and use appropriate, calibrated radiation survey meters. Refer to the section on **Item 9.8 Maintenance, Appendix I, and Appendix K** for more information.
- Required calibration records must be retained for a minimum of 3 years.

Item 9.3: Material Receipt and Accountability

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-451, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-740, 12VAC5-481-840, 12VAC5-481-900, 12VAC5-481-980, 12VAC5-481-1090, 12VAC5-481-3091, 12VAC5-481-3100

Criteria: Licensees must do the following:

- Conduct physical inventories at intervals not to exceed 6 months (or as justified by the applicant) to account for all sealed sources.
- Maintain records of receipt, transfer, and disposal of self-shielded irradiators.

Discussion: While loss, theft, or misplacement of most self-shielded irradiators is unlikely because of their size and weight, accountability for licensed materials must be ensured. Many licensees record use of self-shielded irradiators in a logbook. Licensees are also required to conduct leak tests of irradiator sealed source(s) at the frequency specified in the SDR Certificate. Since both of these activities require that an individual approach the irradiator, records of use and leak tests may be used as part of an accountability program. For more information, see **Item 9.6** ‘Operating and Emergency Procedures’ and **Item 9.7** ‘Leak Tests’ in this guide. However, since some irradiators may not be in use or are used rarely, the agency expects licensees to physically approach and account for all sealed sources at least every 6 months.

‘Cradle to Grave’ accountability refers to maintaining the radioactive material from the moment it becomes a part of your organization through performing the physical inventories (ensuring the material’s location, etc) until it leaves your organization (through transfer, return to manufacturer/distributor, or disposal to properly licensed facility).

Receipt, transfer, and disposal records must be maintained for the times specified in **Table 5**. For materials transferred or disposed of, the date of the transfer or disposal, name and license number of the recipient, description of the affected radioactive material (e.g., radionuclide, activity, manufacturer's (or distributor's) name and model number, serial number).

Maintain inventory records that contain the following types of information:

- Radionuclide and amount (in units of Bq or curies) of radioactive material in each sealed source;
- Manufacturer's name, model number, and serial number of each sealed source;
- Manufacturer's name, model number, and serial number of each device containing depleted uranium or radioactive material;
- Location of each sealed source and device;
- Date of the inventory; and
- Name of individual performing inventory; and
- For materials transferred or disposed of, the date of the transfer or disposal, name and license number of the recipient, description of the affected radioactive material (e.g., radionuclide, activity, manufacturer’s (or distributor’s) name and model number, serial number).

Information on locations where irradiators are used or stored are records important to decommissioning and required by **12VAC5-481-450 C**.

Table 5. Record Maintenance

Type of Record	How Long Record Must be Maintained
Receipt	For as long as the material is possessed until 3 years after transfer or disposal
Transfer	For 3 years after transfer
Disposal	Until VDH terminates the license
Important to decommissioning *	Until the site is released for unrestricted use

* See the **Item 7.1** ‘Financial Assurance and Recordkeeping for Decommissioning’.

Item 9.4: Occupational Dose

Rule: 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-700, 12VAC5-481-710, 12VAC5-481-750, 12VAC5-481-760, 12VAC5-481-770, 12VAC5-481-1040, 12VAC5-481-1130, 12VAC5-481-1140, 12VAC5-481-2280

Criteria: Applicants must do either of the following:

- Perform a prospective evaluation demonstrating that unmonitored individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits as shown in **Table 6**.

OR

- Provide dosimetry as follows:
 - Personnel dosimeters which are processed and evaluated by a National Voluntary Laboratory Accreditation Program (NVLAP) approved processor and are exchanged at a frequency recommended by the processor; or
 - Direct or indirect reading pocket ionization chambers that:
 - Are assigned to a single individual whose accumulated dose is read, recorded, and the chamber recharged, as appropriate, before the chamber is assigned to another individual
 - Have a range of 0 to at least 2 mSv (200 mrem)
 - Are checked at intervals not to exceed one year for correct response to radiation
 - Read within $\pm 20\%$ of the true radiation exposure
 - Are used under a program that prescribes action to evaluate the individual’s dose

Table 6. Occupational Dose Limits for Adults

Occupational Dose Limits for Adults (12VAC5-481-640)	
<u>Body Location</u>	<u>Dose (Annual)</u>
Total Effective Dose Equivalent (Dose to Whole Body)	0.05 Sv (5 Rem)
Dose to the skin and extremities*	0.5 Sv (50 Rem)

Dose to lens of the eyes	0.15 Sv (15 Rem)
*Extremities includes the arms below the elbows and the legs below the knees	

Discussion: Under conditions of routine use and maintenance, the typical self-shielded irradiator user does not require a personnel monitoring device (dosimetry). However, individuals who perform non-routine maintenance do require personnel monitoring devices. **Appendix L** provides guidance on performing a prospective evaluation demonstrating that self-shielded irradiator users are not likely to exceed 10% of the applicable limits and thus, are not required to have personnel dosimetry.

When personnel monitoring is needed, most licensees use either film badges, OSLs or other approved similar devices that are supplied by a NVLAP-approved processor. The exchange frequency for film badges is usually monthly due to technical concerns about film fading. The exchange frequency for OSLs is usually quarterly. Applicants should verify that the processor is NVLAP-approved. Consult with the NVLAP-approved processor for its recommendations for exchange frequency and proper use.

Some licensees use self-reading dosimeters in lieu of processed dosimetry. This is acceptable if the criteria above are met. See ANSI N322, *"Inspection and Test Specifications for Direct and Indirect Reading Quartz Fiber Pocket Dosimeters"*, for more information.

Note: Some licensees choose to provide personnel dosimetry to their workers for reasons other than compliance with VDH requirements (e.g., to respond to worker requests).

References: National Institute of Standards and Technology (NIST) Publication 810, *"National Voluntary Laboratory Accreditation Program Directory"*, is published annually and is available electronically at <http://ts.nist.gov/nvlap>. NIST Publication 810 can be purchased from GPO, whose URL is <http://www.gpo.gov>. ANSI N322 may be ordered electronically at <http://www.ansi.org> or by writing to: ANSI, 1430 Broadway, New York, NY 10018.

Item 9.5: Public Dose

Rule: 12VAC5-481-10, 12VAC5-481-630, 12VAC5-481-720, 12VAC5-481-730, 12VAC5-481-840, 12VAC5-481-1050, 12VAC5-481-1110, 12VAC5-481-2980, 12VAC5-481-3080

Criteria: Licensees must do the following:

- Ensure that licensed self-shielded irradiators will be used, transported, and stored in such a way that members of the public will not receive more than 1 mSv (100 mrem) in one year, and the dose in any unrestricted area will not exceed 0.02 mSv (2 mrem) in any one hour, from licensed operations.
- Control and maintain constant surveillance over self-shielded irradiators that are not in storage and secure stored self-shielded irradiators from unauthorized access, removal, or use.

Discussion: Public dose is defined in **12VAC5-481-10** as *"the dose received by a member of the public from exposure to sources of radiation released by a licensee or registrant, or to any other source of radiation under the control of a licensee or registrant."* Public dose excludes doses

received from background radiation and from medical procedures. Whether the dose to an individual is an occupational dose or a public dose depends on the individual's assigned duties. It does not depend on the area (restricted, controlled, or unrestricted) the individual is in when the dose is received.

In the case of self-shielded irradiators, members of the public include persons who work or may be near locations where self-shielded irradiators are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or stored.

Irradiators should be located away from occupied areas and secured to prevent unauthorized use or removal. Security procedures described in **Item 8** 'Facilities and Equipment' and **Item 9.6** 'Operating and Emergency Procedures' should be effective in limiting the exposure to the public during use or storage. Public dose is controlled, in part, by ensuring that irradiators are secure (e.g., located in a locked area) to prevent unauthorized access or use. Most self-shielded irradiators are massive [i.e., hundreds of kilograms (pounds) and the size of file cabinets], thus not likely to be easily removed from their intended location.

Smaller units, however, such as those used to calibrate TLDs, are more easily moved and should be located in a locked area or bolted in place. Irradiator use is usually restricted by controlling access to the keys needed to operate the irradiator and/or to keys to the locked irradiator area. Only authorized users should have access to these keys.

Public dose is also affected by the choice of storage and use locations and conditions. Since a self-shielded irradiator presents a radiation field, it must be located so that the radiation level in an unrestricted area (e.g., an office or the exterior surface of an outside wall) does not exceed 1 mSv (100 mrem) in a year or 0.02 mSv (2 mrem) in any one hour. Use the concepts of time, distance, and shielding when choosing storage and use locations. Decreasing the time spent near an irradiator, increasing the distance from the irradiator, and using shielding (i.e., brick, concrete, lead, or other solid walls) will reduce the radiation exposure.

Licensees can determine the radiation levels adjacent to the irradiator location either by calculations or a combination of direct measurements and calculations using some or all of the following: typical known radiation levels provided by the irradiator manufacturer (or distributor), the inverse square law to evaluate the effect of distance on radiation levels, occupancy factor to account for the actual presence of the member of the public, and limits on the use of self-shielded irradiator(s). See **Appendix M** for an example.

If, after making an initial evaluation, a licensee changes the conditions used for the evaluation (e.g., changes the location of irradiators, changes the type or frequency of irradiator use, adds self-shielded irradiators, changes the occupancy of adjacent areas), then the licensee must perform a new evaluation to ensure that the public dose limits are not exceeded and take corrective action, as needed.

During agency inspections, licensees must be able to provide documentation demonstrating, by measurement or calculation, that the TEDE to the individual likely to receive the highest dose from the licensed operation does not exceed the annual limit for members of the public. See **Appendix M** for examples of methods to demonstrate compliance.

Item 9.6: Operating and Emergency Procedures

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-451, 12VAC5-481-630, 12VAC5-481-740, 12VAC5-481-750, 12VAC5-481-840, 12VAC5-481-860, 12VAC5-481-880, 12VAC5-481-900, 12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150, 12VAC5-481-2260

Criteria: Before using an irradiator, licensees must do the following:

- Develop, implement, and maintain model-specific operating and emergency procedures containing the following elements:
 - An analysis of each type of material to be placed in the irradiator to ensure that it is compatible with the irradiator's design or to determine if any special safety procedures are needed
 - Instructions for using the self-shielded irradiator and performing routine maintenance, according to the manufacturer's (or distributor's) written recommendations and instructions
 - Instructions for maintaining security to prevent unauthorized use, access, or removal of self-shielded irradiators and the associated sealed sources
 - Steps to take to keep radiation exposures ALARA
 - Steps to maintain accountability
 - Steps to control access to malfunctioning or damaged irradiator
 - Steps to take, and whom to contact (e.g., RSO, local officials), when an irradiator malfunctions or has been damaged.

AND

- Provide copies of operating and emergency procedures to all users.
- Maintain a current copy of operating and emergency procedures at each irradiator's control panel (or, if this is not practicable, post a notice describing the procedures and stating where they may be examined).

Discussion: When used as designed, properly functioning self-shielded irradiators pose little radiation safety risk. However, improper maintenance, irradiating material incompatible with an irradiator's design, or operating an irradiator in an environment other than that recommended by the manufacturer (or distributor), could lead to damage or malfunction of an irradiator and elevated exposure rates in the irradiator's immediate vicinity. Operating and emergency procedures should be developed to minimize these risks, while keeping radiation exposures ALARA. These procedures must be model-specific to account for potentially significant differences in irradiator design and construction that lead to manufacturers (or distributors) providing different instructions and recommendations for operating and maintaining irradiators.

Sources contained in many self-shielded irradiators are designed to deliver significant doses in short periods of time. Although self-shielded irradiators are safe when used correctly, unauthorized access to the irradiator or the irradiator's sources by untrained individuals could lead to a life-threatening situation. Therefore, operating procedures will also need to address access control and accountability. Many licensees achieve access control by permitting only AUs or the RSO to have access to the keys for the irradiator and/or the irradiator area. Accountability of an operating irradiator may be ensured by using a logbook to record irradiator use, maintenance, service calls, and sealed source leak tests. Each activity requires an individual to interact in some way with the irradiator and thereby verify its presence. For sources contained in irradiators that are not actively used, licensees would need to find other methods to maintain accountability, such as conducting inventories.

Licenses must post current copies of the operating procedures applicable to licensed activities (e.g., at the irradiator control panel). If posting of a document is not practicable, the licensee may post a notice which describes the document and states where it may be examined.

Emergency procedures should be developed to address a spectrum of incidents (e.g., interlock failure, flood, earthquake). Emergency response procedures should contain the following:

- Leave the irradiator room to reduce radiation exposure
- Control access (e.g., lock door)
- Contact the individual responsible for the irradiator program for further instructions and to initiate emergency response actions. Telephone numbers should be posted or easily accessible and should include the responsible individual, the irradiator manufacturer, distributor, or its representative, fire department, emergency response organizations, and the agency

VDH Emergency Response Telephone Numbers:
(804) 864-8150 during office hours and
(804) 674-2400 or (800) 468-8892 for 24-hr emergency
response

- Survey areas outside the irradiator room to determine whether further restriction of the area is necessary to ensure that no one can enter the area if the radiation level exceeds 0.02 mSv (2 mrem) per hour
- As appropriate, require timely reporting to the agency according to **12VAC5-481-1090**, **12VAC5-481-1100**, **12VAC5-481-1110**, and **12VAC5-481-1150**.

The agency must be notified when a self-shielded irradiator is lost, stolen, or other conditions occur. The RSO must be proactive in evaluating whether agency notification is required. Refer to **Appendix N** and the regulations (**12VAC5-481-1090**, **12VAC5-481-1100**, **12VAC5-481-1110**, and **12VAC5-481-1150**) for a description of when and where notifications are required.

Appendix O provides information for applicants to consider when developing their procedures for self-shielded irradiators.

Note:

- Licenses authorizing J. L. Shepherd Mark I or Model 81-22 irradiators will be conditioned to require compliance with the terms of the Order in **Appendix E**. Applicants requesting these irradiators must ensure that their operating and emergency procedures address these requirements.
- Before using a new model irradiator, licensees need to revise operating and emergency procedures to include procedures specific to the new irradiator.

Item 9.7: Leak Tests

Rule: **12VAC5-481-740**, **12VAC5-481-750**, **12VAC5-481-1010**, **12VAC5-481-1150**

Criteria: VDH requires testing to determine whether there is any radioactive leakage from the source in the device. The agency finds testing to be acceptable if it is conducted by an

organization approved by VDH, the NRC or another Agreement State or according to procedures approved by VDH.

Discussion: Licensees will perform leak tests at six-month intervals or as approved in the SDDR Certificate. The measurement of the leak-test sample is a quantitative analysis requiring that instrumentation used to analyze the sample is capable of detecting 185 Bq (0.005 microcurie) of radioactivity.

Manufacturers, consultants, and other organizations may be authorized by VDH, the NRC or another Agreement State to either perform the entire leak test sequence for other licensees or provide leak test kits to licensees. In the latter case, the licensee is expected to take the leak test sample according to the self-shielded irradiator manufacturer's (or distributor's) and the kit supplier's instructions and return it to the kit supplier for evaluation and reporting results. Leak test samples should be collected at the most accessible area where contamination would accumulate if the sealed source were leaking. Licensees may also be authorized to conduct the entire leak test sequence themselves.

Note:

- Alternative responses will be reviewed using the criteria listed above.
- If a self-shielded irradiator is added to an existing license, that license might already authorize the licensee to perform the entire leak test sequence. In this case, the licensee may perform the leak testing on the irradiator according to the procedures previously approved on its license.

References: See Section 8.10.8 and Appendix O of NRC NUREG 1556 Vol. 18 “*Program Specific Guidance about Service Provider Licenses*”, and is available electronically at NRC’s web site, <http://www.nrc.gov>.

Item 9.8: Maintenance

Rule: 12VAC5-481-450, 12VAC5-481-490, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-640, 12VAC5-481-980

Criteria: Licensees must routinely maintain self-shielded irradiators according to the manufacturer's (or distributor's) written recommendations and instructions. For self-shielded irradiators, radiation safety procedures for routine maintenance must consider ALARA and ensure that the irradiator functions as designed and source integrity is not compromised.

In this guide, ‘non-routine maintenance’ means any repair, removal, replacement, or alteration involving: electrical and mechanical systems that control source or shielding movement, the irradiator's shielding or sealed source, safety interlocks, any component that may affect safe operation of the irradiator, or any other activities during which personnel could receive radiation doses exceeding VDH limits.

Non-routine maintenance must be performed by the self-shielded irradiator manufacturer (or distributor) or a person specifically authorized by VDH, the NRC or another Agreement State. Requests for specific authorization to perform non-routine maintenance (see **Appendix I**) must demonstrate that personnel performing the work do the following:

- Have adequate training and experience

- Use equipment and procedures that ensure compliance with regulatory requirements, and consider ALARA
- Ensure that the self-shielded irradiator functions as designed and that source integrity is not compromised.

Discussion: NRC IN 96-35, "*Failure of Safety Systems on Self-Shielded Irradiators because of Inadequate Maintenance and Training*", dated June 11, 1996, emphasizes the importance of proper maintenance and describes two incidents in which safety interlocks on self-shielded irradiators failed to prevent inadvertent exposure. Generally, before any maintenance or repair work is done, licensees need to determine (and assure themselves of the adequacy of) the following:

- The tasks to be performed
- The protocol or procedures to be followed
- The radiation safety procedures including possible need for compensatory measures (e.g., steps taken to compensate for lack of or reduced shielding)
- ALARA considerations
- Training and experience of personnel performing the work
- The qualification of parts, components, other materials to be used in the irradiator
- The tests (to be performed before the irradiator is returned to routine use) to ensure that it functions as designed.

VDH permits self-shielded irradiator licensees to perform routine maintenance of the irradiator provided they follow the self-shielded irradiator manufacturer's (or distributor's) written recommendations and instructions. Although manufacturers (or distributors) may use different terms, 'routine maintenance' includes, but is not limited to, cleaning, lubrication, changing batteries, relays or fuses. Routine maintenance does **not** include any activities that involve the source, source drive mechanism, or removing the shielding or source and any other activities during which personnel could receive radiation doses exceeding VDH limits.

The VDH license will require that non-routine maintenance (as defined above) be performed only by the manufacturer (or distributor) or other persons specifically licensed by VDH, the NRC or another Agreement State to perform such services. Most licensees do not perform non-routine maintenance because they must have specialized equipment and technical expertise to perform these activities. Applicants seeking authorization to perform non-routine maintenance must submit specific procedures for review. See **Appendix I** for more information.

Note: Information requested in **Appendix I** will be reviewed on a case-by-case basis; if approved, the license will contain a condition authorizing the licensee to perform non-routine maintenance.

References: NRC INs are available electronically at NRC's web site, <http://www.nrc.gov>.

Security Program

Rule: 12VAC5-481-451, 12VAC5-481-840, 12VAC5-481-1151

Criteria: Licensees must ensure the security and control of licensed material.

Discussion: 12VAC5-481-840 requires licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage.

12VAC5-481-1151 requires that each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source complete and submit a National Source Tracking Transaction Report (NSTS). The NSTS is a secure, accessible, and easy-to-use computer system that tracks high risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay enough to no longer be of concern.

12VAC5-481-451 requires licensees to implement enhanced security to control access to radioactive materials in quantities of concern (RAMQC) and to protect sensitive security related information. The same regulation also requires fingerprinting and criminal history checks for all individuals with unescorted access to RAMQC. The specific radionuclides and associated thresholds were based on the Category 1 and Category 2 quantities described in International Atomic Energy Agency's "*Code of Conduct on the Safety and Security of Radioactive Sources.*"

Please contact the agency for questions regarding the security of licensed material or these regulations.

Item 9.9: Transportation

Rule: 12VAC5-481-100, 12VAC5-481-451, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-840, 12VAC5-481-2980, 12VAC5-481-3000, 12VAC5-481-3010, 12VAC5-481-3020, 12VAC5-481-3070, 12VAC5-481-3080, 12VAC5-481-3091, 12VAC5-481-3100, 12VAC5-481-3110, 12VAC5-481-3130, 49 CFR Parts 171-178

Criteria: Applicants must develop, implement, and maintain safety programs for transport of radioactive material to ensure compliance with VDH and DOT regulations.

Discussion: Most irradiator licensees chose to transfer possession of radioactive materials to an irradiator manufacturer, distributor, or service licensee licensed with VDH, the NRC or another Agreement State who then acts as the shipper. The manufacturer, distributor, or service licensee is subject to the provisions of 12VAC5-481-3000 or 12VAC5-481-3010, as appropriate. They are responsible for proper packaging of the radioactive materials and compliance with VDH and DOT regulations. Licensees who do this must ensure that the manufacturer, distributor, or service licensee:

- Is authorized to possess the irradiator at temporary job sites (e.g., at the irradiator location)
- Actually takes possession of the irradiator under its license
- Uses an approved Type B package
- Is registered with NRC as a user of the Type B package

- Has a VDH, NRC or another Agreement State approved QA plan.

For each shipment, it must be clear who possesses the licensed material and is responsible for proper packaging of the radioactive materials and compliance with VDH and DOT regulations.

The general license in **12VAC5-481-2980** provides the authorization used by most licensees to transport, or offer for transport, packages of radioactive material and specifies certain conditions. Most self-shielded irradiators contain quantities of radioactive material that require using a Type B package. Before offering a Type B package for shipment, the licensee needs to be registered as a user of the package and have an NRC-approved quality assurance (QA) plan, two of the requirements under the **12VAC5-481-3000** general license. For information about QA plans, see Rev. 1 of NRC RG 7.10, "*Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*", dated June 1986. For further information about registering as a user of a package, contact NRC's Spent Fuel Project Office (SFPO) by calling NRC's toll-free number 800-368-5642 and asking for extension 415-8500. For information about associated fees, contact NRC's OCFO by calling NRC's toll-free number 800-368-5642 and asking for extension 415-7554.

During an inspection, the agency uses the provisions of **12VAC5-481-2980** to examine and enforce various DOT requirements applicable to irradiator licensees. **Part 1 of Appendix Q** lists major DOT regulations and **Part 2** contains a sample bill of lading.

Before the adoption of the requirements of **10 CFR Part 71** in 1966, self-shielded irradiators could be transported without being evaluated under the hypothetical accident conditions that are now incorporated in **10 CFR 71**. Because pre-1966 irradiators are not certified shipping packages, transporting them may require transferring the sealed source from the irradiator to a certified Type B package or using a certified package for the irradiator containing the sealed sources. Only if these options are not viable will VDH consider a licensee's request for an exemption for a one-time shipment from **12VAC5-481-3130**. Exemption requests should contain the information described in Part 3 of **Appendix Q**. In addition to a VDH exemption, the licensee may also need a DOT exemption; contact DOT's Office of Hazardous Materials Technology at 202-366-4545 for additional information.

References: "*A Review of Department of Transportation Regulations for Transportation of Radioactive Materials (1998 revision)*" can be obtained by calling DOT's Office of Hazardous Material Initiatives and Training at (202) 366-4425 or at the following website, <http://hazmat.dot.gov/>. NRC Regulatory Guides are available electronically at NRC's web site, <http://www.nrc.gov>.

Item 9.10: Minimization of Contamination

Rule: **12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-630, 12VAC5-481-740, 12VAC5-481-1150, 12VAC5-481-1161**

Criteria: Applicants for new licenses must describe how facility design and procedures for operation will minimize, to the extent practicable, contamination of the facility and the environment, facilitate eventual decommissioning, and minimize, to the extent practicable, the generation of radioactive waste.

Discussion: All applicants for new licenses need to consider the importance of designing and operating their facilities to minimize the amount of radioactive contamination generated at the

site during its operating lifetime and to minimize the generation of radioactive waste during decontamination. Irradiator applicants usually do not need to address these issues as a separate item since they are included in responses to other items of the application.

Sealed sources and devices that are approved by the NRC or other Agreement States and located and used according to their SSDR Certificates usually pose little risk of contamination. Leak tests performed as specified in the SSDR Certificate should identify defective sources. Leaking sources must be immediately withdrawn from use and decontaminated, repaired, or disposed of according to VDH requirements. These steps minimize the spread of contamination and reduce radioactive waste associated with decontamination efforts. Other efforts to minimize radioactive waste do not apply to programs using only sealed sources and devices that have not leaked.

Note: The agency will consider that the above criteria has been met if the applicant's responses meet the criteria in the following items: **Item 7** 'Radioactive Material'; **Item 9.6** 'Operating and Emergency Procedures'; **Item 9.7** 'Leak Test'; **Item 10** 'Disposal, Transfer and License Termination'.

Item 10: Disposal, Transfer and License Termination

Item 10.1: Disposal and Transfer

Rule: 12VAC5-481-100, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-630, 12VAC5-481-910, 12VAC5-481-980, 12VAC5-481-2980, 12VAC5-481-3100

Criteria: Licensed materials must be disposed of according to VDH requirements by transfer to an authorized recipient. Appropriate records must be maintained.

Discussion: When disposing of self-shielded irradiators, licensees must transfer them to an authorized recipient. Authorized recipients are the original manufacturer (or distributor) of the irradiator, a commercial firm licensed by VDH, the NRC or another Agreement State to accept radioactive waste from other persons, or another specific licensee authorized to possess the licensed material (i.e., its license specifically authorizes the same radionuclide, form, and use).

Before transferring radioactive material, a licensee must verify that the recipient is properly authorized to receive it using one of the methods described in **12VAC5-481-570**. In addition, all packages containing radioactive sources must be prepared and shipped according to VDH and DOT regulations. Records of the transfer must be maintained as required by **12VAC5-481-100** and **12VAC5-481-571**.

Licenses should promptly dispose of unused irradiators to minimize potential problems of access by unauthorized individuals, use for inappropriate purposes, or improper disposal.

Note: Because of the difficulties and costs associated with disposal of sealed sources, applicants should preplan the disposal. Applicants may want to consider contractual arrangements with the source supplier as part of a purchase agreement.

Item 10.2: Termination of Activities

Rule: 12VAC5-481-100, 12VAC5-481-450, 12VAC5-481-500, 12VAC5-481-510, 12VAC5-481-570, 12VAC5-481-571, 12VAC5-481-1161

Criteria: The licensee must do the following:

- Notify the agency, in writing, within 60 days of:
 - The expiration of its license;
 - A decision to permanently cease licensed activity at the entire site or in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to VDH requirements;
 - No principal activities have been conducted at the entire site under the license for a period of 24 months;
 - No principal activities have been conducted for a period of 24 months in any separate building or outdoor area if it contains residual radioactivity making it unsuitable for release according to VDH requirements.
- Submit a decommissioning plan, if required by **12VAC5-481-510**;
- Decommissioning, as required by **12VAC5-481-510 & 12VAC5-481-1161**;
- Submit to the agency, a completed VDH form ‘Certificate of Disposition of Materials’ (**Appendix B**) and demonstrate that the premises are suitable for release for unrestricted use (e.g. results of final survey); and
- Before a license is terminated, send the records important to decommissioning to the agency as required by **12VAC5-481-571**. If licensed activities are transferred or assigned in accordance with **12VAC5-481-500**, transfer records important to decommissioning to the new licensee.

Discussion: For guidance on the disposition of licensed material, see the **Item 10**, ‘Disposal, Transfer and License Termination’. For guidance on decommissioning records, see **Item 7.1** ‘Financial Assurance and Record Keeping for Decommissioning’. Licensees must use the VDH Form, ‘Certificate of Disposition of Materials’ (**Appendix B**) when submitting for termination of a license.

Item 11: License Fees

For a listing of application fees, please see **12VAC5-490**. On VDH Form, ‘Application for Radioactive Material Authorizing the Use of Self-Shielded Irradiator Devices’ (**Appendix A**), enter the fee category and the amount.

Item 12: Certification

Individuals acting in a private capacity are required to sign and date VDH Form, ‘Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators’ (**Appendix A**). Otherwise, senior representatives of the corporation or legal entity filing the application should sign and date VDH Form, ‘Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators’ (**Appendix A**). **Representatives signing an application must be authorized to make binding commitments and sign official documents on behalf of the applicant.** The agency will return all unsigned applications for proper signature.

Note:

- It is a violation of **12VAC5-481-30** to make a willful false statement or representation on applications or correspondence.
- When the application references commitments, those items become part of the licensing conditions and regulatory requirements.

Security Program

Rule: 12VAC5-481-451, 12VAC5-481-840, 12VAC5-481-1151

Criteria: Licensees must ensure the security and control of licensed material.

Discussion: **12VAC5-481-840** requires licensees to secure radioactive materials from unauthorized removal or access while in storage and to control and maintain constant surveillance over licensed material that is not in storage.

12VAC5-481-1151 requires that each licensee who manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source complete and submit a National Source Tracking Transaction Report. The NSTS is a secure, accessible, and easy-to-use computer system that tracks high –risk radioactive sources from the time they are manufactured or imported through the time of their disposal or export, or until they decay enough to no longer be of concern.

12VAC5-481-451 requires licensees to implement enhanced security to control access to Category 1 and Category 2 quantities radioactive materials and to protect sensitive security related information. The same regulation also requires fingerprinting and criminal history checks for all individuals with unescorted access to Category 1 and Category 2 quantities radioactive materials. The specific radionuclides and associated thresholds were based on the Category 1 and Category 2 quantities described in International Atomic Energy Agency’s “Code of Conduct on the Safety and Security of Radioactive Sources.”

Refer Appendix Q for additional guidance for implementing security plan for physical protection of category 1 and category 2 quantities of radioactive material

Appendix A

VDH Form

‘Application for Radioactive Material License Authorizing the Use of Self-Shielded Irradiators’

The Form is located at: <http://www.vdh.virginia.gov/radiological-health/radiological-health/materials/forms-postings/>

Attachment A

Self-Shielded Irradiator Applicant's Checklist

Yes	No	Item	Material Needed
		Application	Used the correct form (New for new licensees or Renewal for renewing licensees)
		Application	Checked at least one box and filled in all the required information, as needed, for all Items
		Item 5	Attached training information, as needed
		Item 6	Attached training information, as needed
		Item 8	Attached facility diagram AND checked box or attached alternate procedures
		Item 9.6	Checked box and attached procedures
		Item 9.7	Checked at least one box and, if needed, attached alternate procedures including analysis instrumentation information
		Item 9.8	Routine: checked box or attached alternate procedure
		Item 9.8	Non-Routine: checked box or attached information contains all the requirements of Appendix I

Appendix B

VDH Form

‘Certificate of Disposition of Materials’



CERTIFICATE OF DISPOSITION OF MATERIALS

Completion of this form is required to complete termination of a Radioactive Material License as outlined in **12VAC5-481-500**. Failure to provide information will result in this request for termination of a specific license not being processed.

Instructions – Complete all items. Retain one copy and submit original to Virginia Department of Health, Radioactive Materials Program, 109 Governor Street, Room 730, Richmond, VA 23219.

CONTACT INFORMATION

Item 1 Name and Mailing Address of Applicant:	Item 2 Virginia Radioactive Material License Number
	Item 3 Contact Person – Name
	Contact Person - Telephone Number (Include area code)

TERMINATION AND DISPOSITION INFORMATION

The following information is provided in accordance with **12 VAC 5-481-510**. (Check all that apply)

- Item 4** All use of radioactive material authorized under the above referenced license has been terminated.
-
- Item 5** Radioactive contamination has been removed to the levels outlined in **12VAC5-481-1161 B**.
-
- Item 6** All radioactive material previously procured and/or possessed under the authorization granted by the above referenced license has been disposed of as follows. (Check all that apply)
- Transferred to: Name Address

Who is (are) authorized to possess such material under Licensed Number:

Issued by (Licensing Agency):

- Decayed, surveyed and disposed of as non-radioactive waste.
- No radioactive material has ever been procured and/or possessed by the licensee under the authorization granted by the above referenced license.
- Other (Attach additional pages)

-
- Item 7** Attached are radiation surveys or equivalent as specified in **12VAC5-481-510 L**. Specify the survey instrument(s) used and certify that each instrument is properly calibrated as required in **12VAC5-481-510 K**.
-

Item 8 Records required to be maintained for the license termination requested are available at the following location(s):

Name:

Address:

Contact Person Telephone Number: () - X

Additional remarks (Attach additional pages if necessary.)

CERTIFICATION (To be completed by an individual authorized to make binding commitments on behalf of the applicant.)

Item 10.

The undersigned, on behalf of the licensee, hereby certifies that licensable quantities of radioactive material under the jurisdiction of the Virginia Department of Health are not possessed by the licensee. It is therefore requested that the above referenced radioactive material license be terminated.

SIGNATURE - Applicant or Authorized Individual

Date signed

Print Name and Title of above signatory

Appendix C

Sample Correspondence Delegation Letter

SAMPLE CORRESPONDENCE DELEGATION LETTER

[*date*]

[*name and address*]

Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219

To Director Radioactive Material Program:

As [*job title*] of [*name of licensee*], I have delegated authority for all matters pertaining to our Radioactive Material License to [*name of designee*]. [*Name of designee*] has management approval to sign and submit amendment requests to the Virginia Department of Health on behalf of [*name of licensee*]. I understand that license renewals must still be signed by a representative of upper management.

[This document must be signed by a management representative who has independent authority to reassign job duties and/or provide finances, if necessary, to support an effective radiation safety program.]

Signature

Title

Date

Print Name

Appendix D

Information Needed for Transfer of Control Application

Information Needed for Transfer of Control

Licensees must provide full information and obtain the agency's **prior written consent** before transferring control of the license. Provide the following information concerning changes of control by the applicant (transferor and/or transferee, as appropriate). If any items are not applicable, so state.

Control: Control of a license is in the hands of the person or persons who are empowered to decide when and how that license will be used. That control is to be found in the person or persons who, because of ownership or authority explicitly delegated by the owners, possess the power to determine corporate policy and thus the direction of the activities under the license.

Transferee: A transferee is an entity that proposes to purchase or otherwise gain control of a VDH licensed operation.

Transferor: A transferor is a VDH licensee selling or otherwise giving up control of a licensed operation.

1. Provide a complete description of the transaction (transfer of stocks or assets, or merger). Indicate whether the name has changed and include the new name. Include the name and telephone number of a licensee contact who the agency may contact if more information is needed.
2. Describe any changes in personnel or duties that relate to the licensed program. Include training and experience for new personnel.
3. Describe any changes in the organization, location, facilities, equipment or procedures that relate to the licensed program.
4. Describe the status of the surveillance program (surveys, wipe tests, quality control) at the present time and the expected status at the time that control is to be transferred.
5. Confirm that all records concerning the safe and effective decommissioning of the facility will be transferred to the transferee or to the agency, as appropriate. These records include documentation of surveys of ambient radiation levels and fixed and/or removable contamination, including methods and sensitivity.
6. Confirm that the transferee will abide by all constraints, conditions, requirements and commitments of the transferor or that the transferee will submit a complete description of the proposed licensed program.

References: The information above is derived from NRC Information Notice 89-25, Revision 1, "*Unauthorized Transfer of Ownership or Control of Licensed Activities*", which is available at the NRC's webpage at <http://www.nrc.gov>.

Appendix E

J. L. Shepherd Order

J. L. Shepherd Order

**JULY 3, 1984
UNITED STATES
NUCLEAR REGULATORY COMMISSION
URGENT NOTICE**

TO ALL LICENSEES WHO POSSESS J. L. SHEPHERD IRRADIATORS

An NRC licensee recently identified a malfunction in the lock mechanism of its J. L. Shepherd self-shielded irradiator which could have resulted in a radiation overexposure. Although no overexposure appears to have occurred, the potential hazard warrants immediate preventive action. Therefore, we have prepared the enclosed Order which requires the use of radiation survey equipment when the irradiators are being used.

If you possess a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator, do not use it unless you provide appropriate radiation monitoring as specified in the Order. If you do not currently possess the appropriate equipment, you must obtain it before you resume use of your irradiator. Also, you should report any problems to your nearest NRC regional office immediately. Do not attempt to repair an irradiator, or allow anyone else to attempt repairs, unless specific authorization for repair of the irradiator which you possess is provided in an NRC license.

We suggest that you review who has access to your irradiator, and establish strict controls to assure that no untrained personnel have access. Trained persons who continue to use the irradiator should conduct careful radiation surveys as specified in the Order. Irradiator doors should be opened slowly, to minimize any accidental exposure and to avoid "blinking out" of instruments due to high exposure rates. Any unusual meter reading should be taken as evidence of a problem.

We are including in this mailing certain licensees about which we are uncertain whether they possess J. L. Shepherd irradiators. If you do not possess a J. L. Shepherd irradiator, please disregard this notice.

Because this Order is effective immediately, it is important that you notify your radiation safety personnel immediately, and retain this Order with your license records. Questions and comments may be directed to your nearest NRC regional office.

Sincerely,
Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Enclosure: Order Modifying License

**UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D. C. 20555**

ORDER MODIFYING CERTAIN LICENSES (EFFECTIVE IMMEDIATELY)

I

Recently, the Nuclear Regulatory Commission (NRC) staff was notified by a licensee of the failure of a locking mechanism on a self-shielded irradiator which could have resulted in a radiation overexposure. ("Self-shielded" irradiators are designed so that the radioactive source remains in a shielded position at all times, both during storage and during irradiations. Therefore, the irradiators need not be placed in a shielded room.)

The irradiator is a J. L. Shepherd Mark I, containing about 6,000 curies of cesium 137. The unit is operated as follows: (1) With the source in its shielded storage position, the shielded door is opened, (2) materials to be irradiated are placed inside the irradiator chamber, (3) the shielded door is closed, (4) the radioactive source is raised into the irradiation chamber, (5) after irradiation is complete, the source is lowered, and (6) the door is opened for removal of irradiated materials.

The shielded door is interlocked so that it should not open when the radioactive source is in the irradiation chamber. However, in the case reported to NRC, the lock mechanism failed. In such a situation, an operator who opens the shielded door with the source raised could be subjected to substantial radiation exposure. The J. L. Shepherd Model 81-22 irradiator employs an interlock similar to the Mark I.

The NRC staff has examined the irradiator in question and confirmed the defect. Furthermore, a New York City inspector checking a J. L. Shepherd Mark I irradiator in New York reported a malfunctioning interlock system. NRC and the Agreement States are studying the problem further to assess its generic implications.

Based on the foregoing, I have concluded that the possibility of failure of locking mechanisms and/or mechanical timers on J. L. Shepherd Mark I and Model 81-22 irradiators represents a potential radiation hazard warranting immediate preventive action pending further investigation. I have determined, therefore, that the public health, safety, and interest require that the restrictions on the use of such irradiators as prescribed in Section II of this Order should be made immediately effective.

II

Accordingly, pursuant to Sections 81, 116 I, 162 o, and 182 of the Atomic Energy Act of 1954, as amended, and 10 CFR Parts 2 and 30 of the Commission's regulations, IT IS HEREBY ORDERED, EFFECTIVE IMMEDIATELY, THAT:

Each license that authorizes possession of byproduct material in a J. L. Shepherd Mark I or Model 81-22 self-shielded irradiator is hereby amended to add the following conditions:

1. The J. L. Shepherd irradiator shall not be used unless the licensee provides a calibrated and operable radiation survey meter or room monitor for use with the irradiator.
2. The irradiator door shall not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.
3. Each room monitor (a) shall be operable at all times when the irradiator is in use, (b) shall activate a visible and audible alarm when radiation levels exceed 2 millirems per hour, (c) shall be located to detect any radiation escaping from the irradiator door, and (d) shall be located so that it is visible to the irradiator user when he is next to the irradiator.
4. If a room monitor is not installed, a survey meter shall be used (a) to determine the radiation level at the irradiator door when the door is closed, and (b) to check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators shall position themselves so as to minimize exposure to any radiation escaping from the open door.
5. If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee shall stop use of the irradiator and immediately notify the appropriate NRC regional office by telephone.
6. The licensee shall not attempt repair or authorize others to attempt repair of the irradiator except as specifically authorized in a license issued by NRC.

III

Any affected licensee may request a hearing on this Order. A request for a hearing shall be submitted within twenty (20) days of the date of this Order to Mr. R. E. Cunningham, Director, Division of Fuel Cycle and Material Safety, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555, with a copy to the Executive Legal Director, U. S. Nuclear Regulatory Commission, Washington, D. C. 20555. ANY REQUEST FOR A HEARING SHALL NOT STAY THE IMMEDIATE EFFECTIVENESS OF THIS ORDER.

IV

If a hearing is requested, the Commission will issue an Order designating the time and place of any such hearing. If a hearing is held the issue to be considered at such a hearing will be: Whether, on the basis of the matters set forth in Section 1 and II of this Order, this Order should be sustained.

FOR THE NUCLEAR REGULATORY COMMISSION

Richard E. Cunningham, Director
Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards

Dated at Bethesda, Maryland this 3rd day of July, 1984

Appendix F

Guidance on Financial Assurance

Guidance on Financial Assurance

Determining Need for Financial Assurance

If the only radioactive materials possessed are sealed sources in self-shielded irradiators, use **Table 7** to determine if financial assurance is required.

Table 7. Worksheet for Determining Need for Financial Assurance for Self-Shielded Irradiator

Step No.	Description	Cobalt-60	Cesium-137	Strontium-90
1	Activity possessed, in Curies*			
2	Activity requiring financial assurance, in Curies	10,000	100,000	1,000
3	Divide data in Step 1 by data in Step 2 = FRACTION			
4	Add the fractions determined in Step 3			

*For ease of use by most irradiator licensees, this table uses only conventional units. The conversion to SI units is: 1 Ci = 37 GBq.

If the sum of the fractions is greater than or equal to 1, the applicant will need to submit certification of financial assurance or a decommissioning funding plan (**12VAC5-481-450 C**). NRC RG 3.66,(4) "*Standard Format and Content of Financial Assurance Mechanisms Required for Decommissioning Under 10 CFR Parts 30, 40, 70, and 72*", provides sample documents for financial mechanisms. The recommended wording for a Statement of Intent for government licensees is shown below.

Note: NRC RG 3.66 is available electronically at NRC's web site, <http://www.nrc.gov>.

Suggested Wording for a Statement of Intent for a Government Licensee

[*date*]

[*name and address*]

TO: Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219

STATEMENT OF INTENT

As [*Title*] of [*Licensee Name*], I exercise express authority and responsibility to approve funding for decommissioning activities associated with operations authorized by Virginia Department of Health Material License No. [*License Number*]. This authority is established by [*Name of Document(s) Governing Control of Funds*]. Within this authority, I intend to have funds made available when necessary in an amount up to [*Dollar Amount*] to decommission [*Description of Facilities*]. I intend to request and obtain these funds sufficiently in advance of decommissioning to prevent delay of required activities.

A copy of [*Name of Documents*] is attached as evidence that I am authorized to represent [*Licensee Name*] in this transaction.

[SIGNATURE]

[NAME]

[TITLE]

Attachment: As stated

Appendix G

Training Program for Authorized Users and Radiation Safety Officers

Training Program for Authorized Users and Radiation Safety Officers

Course Content

Training may be in the form of lecture, videotape, hands-on, or self-study, and emphasizes practical subjects important to the safe use of the self-shielded irradiator:

- Radiation Safety
 - Radiation vs. contamination
 - Internal vs. external exposure
 - Biological effects of radiation
 - Types and relative hazards of radioactive material possessed
 - ALARA concept
 - Use of time, distance, and shielding to minimize exposure
 - Use of radiation detection instruments.

- Regulatory Requirements
 - Locations of use and storage of radioactive materials
 - Material control and accountability
 - Annual audit of radiation safety program
 - License conditions, amendments, renewals
 - Transfer and disposal
 - Recordkeeping
 - Handling incidents
 - Licensing and inspection by regulatory agency
 - Need for complete and accurate information
 - Employee protection
 - Deliberate misconduct.

- Practical Explanation of the Theory and Operation for Each Irradiator Possessed by the Licensee
 - Routine vs. non-routine maintenance
 - Operating and emergency procedures
 - Prior events involving self-shielded irradiators.

Instructor's Qualifications

The individual preparing and conducting training is qualified as Radiation Safety Officer (RSO) or Authorized User (AU) on a self-shielded irradiator license before giving training.

Training Assessment

Management will ensure that potential RSOs and AUs are qualified to work independently with each type of the licensee's irradiators. This may be demonstrated by written or oral examination or by observation.

Appendix H

Typical Duties and Responsibilities of the Radiation Safety Officer

Typical Duties and Responsibilities of the Radiation Safety Officer

The RSO's duties and responsibilities include ensuring radiological safety and compliance with VDH and DOT regulations and the conditions of the license; see **Table 2**. Typically, these duties and responsibilities include ensuring the following:

- Activities involving licensed material that the RSO considers unsafe are stopped
- Radiation exposures are ALARA
- Posting of required documents, or a notice where the following documents can be found:
 - Required by **12VAC5-481-2260**:
12VAC5-481 'Virginia Radiation Protection Regulations' Part IV, 'Standards for Protection from Radiation' and Part X, 'Notices, Instructions and Reports to Workers; Inspections'; license documents; operating procedures; VDH Form, 'Notice to Employees'
- Development, distribution, implementation, and maintenance of up-to-date operating and emergency procedures
- Possession, installation, relocation, use, storage, repair, and maintenance of self-shielded irradiators are consistent with the limitations in the license, the SSDR Certificate(s), and manufacturer's written recommendations and instructions
- Safety consequences are analyzed before conducting any activities involving repair, use, maintenance, installation, or relocation, which were never previously analyzed
- Individuals installing, relocating, using, maintaining, or repairing self-shielded irradiators are trained and authorized (as described in the license application)
- Prospective evaluations are performed demonstrating that individuals are not likely to receive, in one year, a radiation dose in excess of 10% of the allowable limits or personnel monitoring devices are provided
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals, and records of the results of such monitoring are maintained
- Self-shielded irradiators are properly secured
- Documentation is maintained to demonstrate, by measurement or calculation, that the TEDE to the individual member of the public likely to receive the highest dose from the licensed operation does not exceed the annual limit in **12VAC5-481-720**.

- Proper authorities are notified of incidents such as damage to or malfunction of self-shielded irradiators, fire, or theft
- Unusual occurrences involving the self-shielded irradiators (e.g., malfunctions or damage) are investigated, cause(s) and appropriate corrective action(s) are identified, and timely corrective action(s) are taken
- Radiation safety program audits are performed at least annually and documented
- When the licensee identifies violations of **12VAC5-481 ‘Virginia Radiation Protection Regulations’** or license conditions or program weaknesses, the licensee develops, implements, and documents corrective actions
- Licensed material is transported in accordance with all applicable DOT requirements
- Licensed material is disposed of properly
- Appropriate records are maintained
- Up-to-date license is maintained and amendment and renewal requests are submitted in a timely manner

Appendix I

Information Needed to Support Applicant's Request to Perform Non-Routine Maintenance

Information Needed to Support Applicant's Request to Perform Non-routine Maintenance

Review **Item 9.8** 'Maintenance' which discusses, in general, licensee responsibilities before any maintenance or repair is performed.

Non-routine maintenance includes repairs, removal, replacement, or alterations involving:

- Electrical and mechanical systems and components that control source or shielding movement
- Self-shielded irradiator's shielding or sealed source(s)
- Safety interlocks
- Any other component which may affect safety operation of the device
- Any other activities during which personnel could receive radiation doses exceeding VDH limits

If this maintenance or repair is not performed properly with attention to radiation safety principles, the self-shielded irradiator may not operate as designed and personnel performing these tasks could receive radiation doses exceeding VDH limits. Non-routine maintenance should be performed only by qualified and specifically authorized individuals. Self-shielded irradiator licensees should conduct these operations only after their procedures have been evaluated and specifically approved by license condition. Also, any non-manufacturer- (non-distributor-) supplied replacement components or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer (or distributor) needs to be evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration. Licensees also need to ensure that, after maintenance or repair is completed, the irradiator is tested and functions as designed, before the unit is returned to routine use.

Accordingly, applicants wishing to perform non-routine maintenance must provide the following information, as appropriate:

- Describe the types of non-routine maintenance to be performed. The principal reason for obtaining this information is to assist in the evaluation of the qualifications of individuals who will conduct the work and the radiation safety procedures they will follow.
- Identify who will perform non-routine maintenance, their training and experience, and why they are competent to perform non-routine maintenance. Adequate training and experience includes the following:
 - Previous experience in non-routine maintenance and radiation safety training
 - Vender maintenance certification
 - Technician(s) using pre-planned procedures with direct health physics supervision
- Submit procedures for non-routine maintenance. These procedures should ensure the following:
 - Doses to personnel and members of the public are within regulatory limits and ALARA
 - The source is secured against unauthorized access or removal
 - Appropriate labels and signs are used
 - Manufacturer's (distributor's) written instructions and recommendations are followed

- Any non-manufacturer (non-distributor) supplied replacement components or the use of materials (e.g., lubricants) other than those specified or recommended by the manufacturer (or distributor) are evaluated to ensure that they do not degrade the engineering safety analysis performed and accepted as part of the device registration
 - Before being returned to routine use, the self-shielded irradiator is tested to verify that it functions as designed and source integrity is not compromised.
- Confirm that individuals performing non-routine maintenance on irradiators will always wear both whole body and extremity monitoring devices
 - Verify possession of at least one instrument that meets the description for survey meters used with moving-source irradiators in ‘Radiation Monitoring Instrument Specifications and Survey Instrument Calibration Program’ section of **Appendix K**.
 - Describe steps to be taken to ensure that radiation levels in areas where non-routine maintenance will take place do not exceed **12VAC5-481-720** limits. For example, applicants can do the following:
 - Commit to performing surveys with a survey instrument (as described above);
 - Specify where and when surveys will be conducted during non-routine maintenance; and
 - Commit to maintaining, for 3 years for the date of the survey, records of the survey (e.g., who performed the survey, date of the survey, instrument used, measured radiation levels correlated to location of those measurements), as required by **12VAC5-481-1050**.

Appendix J

Self-Shielded Irradiator Audit Checklist

Self-Shielded Irradiator Audit Checklist

Note: All areas indicated in audit notes may not be applicable to every license and may not need to be addressed during each audit. For example, licensees do not need to address areas which do not apply to the licensee's activities and activities which have not occurred since the last audit need not be reviewed at the next audit.

Date of This Audit _____

Date of Last Audit _____

Next Audit _____

Auditor: _____
(Signature)

Date _____

Management Review _____
(Signature)

Date _____

Audit History

- A. Were previous audits conducted annually? [12VAC5-481-630]
- B. Where records of previous audits maintained? [12VAC5-481-990]
- C. Were any deficiencies identified during last two audits or two years, whichever is longer?
- D. Were corrective actions taken? (Look for repeated deficiencies).

Organization and Scope of Program

- A. Radiation Safety Officer
 - 1. If the RSO was changed, was license amended?
 - 2. Does new RSO meet VDH training requirements?
 - 3. Is RSO fulfilling his/her duties?
 - 4. To whom does RSO report?

B. Licensed Material

1. Does the license authorize all of the VDH-regulated radioactive material contained in self-shielded irradiators?
2. Does the total amount of radioactive material possessed require financial assurance?
[12VAC5-481-450 C]

C. Are the self-shielded irradiators as described in the Sealed Source and Device Registration (SSDR) Certificate? Have copies of (or access to) SSDR Certificates? Have manufacturer's (or distributor's) manuals for operation and maintenance?

D. Are the actual uses of self-shielded irradiators consistent with the authorized uses listed on the license?

E. If the mailing address or places of use changed, was the license amended?

F. If control of license transferred or bankruptcy filed, was agency prior consent obtained or notification made, respectively?

G. Has a National Source Tracking Transaction Report been completed and submitted if required by 12VAC5-481-1151?

H. Has a security program been implemented to control access to radioactive materials of concern and to protect sensitive security related information required by 12VAC5-481-451?

Training and Instructions to Workers

A. Were all workers who are likely to exceed 1 mSv (100 mrem) in a year instructed per 12VAC5-481-2270? Was refresher training provided, as needed [12VAC5-481-2270]?

B. Did each authorized user and person independently performing routine or non-routine maintenance attend license-required training before working with self-shielded irradiators?

C. Are training records maintained for each individual?

D. Did interviews with workers reveal that they know the emergency procedures and repair, maintenance, and relocation limitations?

E. Did this audit include observations of operators using the self-shielded irradiators? Performing routine or other authorized maintenance?

F. Did the audit identify any operator error in reporting maintenance and repair or operation issues to the RSO for review before starting work?

Radiation Survey Instruments

- A. Describe the survey instruments possessed:
1. Do they meet the agency's criteria?
 2. Are they appropriate for the source type(s)?
 3. Are they checked for function before use?
 4. If they are used with moving-source irradiators or during non-routine maintenance, are they calibrated as required? [**12VAC5-481-750**]
- B. If the licensee does not possess a survey meter, are specific plans made to have one available?
- Location: _____ Location/Operation verified: _____
- C. Are calibration records, if required, maintained? [**12VAC5-481-1000**]
- D. For J. L. Shepherd Mark I or Model 81-22 irradiator, check for compliance with license condition

Self-Shielded Irradiator Inventory and Location

- A. Is a record kept showing the receipt of each self-shielded irradiator? [**12VAC5-481-100, 12VAC5-481-571**]
- B. Has the location(s) changed since the last audit?

Personnel Radiation Protection

- A. Are ALARA considerations incorporated into the radiation protection program? [**12VAC5-481-630**]
- B. Were prospective evaluations performed showing that unmonitored users receive $\leq 10\%$ of limit? [**12VAC5-481-760**]
- C. Did unmonitored users' activities change during the year which could put them over 10% of limit?
- D. If yes to C above, was a new evaluation performed?
- E. Is external dosimetry required (users received $>10\%$ of limit)? Is dosimetry provided to users?

1. If processed dosimetry:
 - a. Is the dosimetry supplier NVLAP-approved? [12VAC5-481-750]
 - b. Are dosimetry reports reviewed by the RSO when they are received?

2. If self-reading dosimeters:
 - a. Have a range of zero to at least 2 mSv (200 mrem)?
 - b. Are checked at periods not to exceed one year for correct response to radiation?
 - c. Are read within $\pm 20\%$ of the true radiation exposure?
 - d. Are used under a program that prescribes action to evaluate the individual's dose?

- F. Are the dosimeters exchanged or read at the license required frequency?

- G. Are the records agency forms or equivalent? [12VAC5-481-1000, 12VAC5-481-1040]
 1. VDH Form, 'Occupational Exposure Record per Monitoring Period' completed?

- H. Declared pregnant worker/embryo/fetus
 1. If a worker declared her pregnancy, did licensee comply with 12VAC5-481-710?
 2. Were records kept of embryo/fetus dose per 12VAC5-481-1040?

- I. Are records of exposures, surveys, monitoring, and evaluations maintained? [12VAC5-481-990, 12VAC5-481-1000, 12VAC5-481-1020, 12VAC5-481-1030, 12VAC5-481-1040, 12VAC5-481-1050]

- J. Are annual exposure reports given to workers who receive > 100 mrem per year? [12VAC5-481-2280]

Public Dose

- A. Are self-shielded irradiators located and used in a manner to keep doses below 1 mSv (100 mrem) in a year? [12VAC5-481-720]

- B. Has a survey or evaluation been performed per 12VAC5-481-730?

- C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

- D. Do unrestricted area radiation levels exceed 0.02 mSv (2 mrem) in any one hour?
[12VAC5-481-720]
- E. Are self-shielded irradiators being used or stored in a manner that would prevent unauthorized access or removal? [12VAC5-481-840]
- F. Records maintained? [12VAC5-481-1000, 12VAC5-481-1050]

Operating and Emergency Procedures

- A. Have operating and emergency procedures been developed?
- B. Do they contain the required element?
- C. Does each operator have a current copy of the operating and emergency procedures? Maintain copy at each irradiator's control panel or post notice indicating where to obtain copy?
- D. Did any emergencies occur?
 - 1. If so, were they handled properly by operator?
 - 2. Were appropriate corrective actions taken?
 - 3. Was agency notification or reporting required? [12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150]
- E. For J. L. Shepherd Mark I or Model 81-22 irradiator, check for compliance with license condition
- F. Were operating or emergency procedures changed since last audit? If so, before new procedures were implemented:
 - 1. Did licensee management and the RSO approve?
 - 2. Did affected staff receive training?
 - 3. Are the changes consistent with license conditions? Licensee commitments?
 - 4. Do the changes degrade safety?

Leak Tests

- A. Was each sealed source leak tested every 6 months (or at other license prescribed intervals)?
- B. Was the leak test performed as described in correspondence with VDH and according to the license?
- C. Are records of results retained with the appropriate information included?
- D. Were any sources found leaking and if yes, was the agency notified?

Maintenance of Self-shielded Irradiators

- A. Are manufacturer's (or distributor's) written procedures followed for routine (not safety critical) cleaning and lubrication and mechanical/electrical maintenance and repair of self-shielded irradiators?
- B. Was non-routine maintenance performed?
- C. If yes, was it performed according to license requirements (e.g., extent of work, individuals performing the work, procedures, dosimetry, survey instrument, compliance with dose limits)?
- D. Since the last audit, did operator(s) report a need for non-routine maintenance and repair to the RSO before requesting or conducting the work?

Transportation

- A. Were self-shielded irradiator(s) or sources shipped since the last audit?
- B. If so, was **12VAC5-481 'Virginia Radiation Protection Regulations' Part XIII 'Transportation of Radioactive Material'** requirements followed?
 - 1. DOT-Type A or Type B packages used?[**12VAC5-481 'Virginia Radiation Protection Regulations' Part XIII, 49 CFR 173.415, 49 CFR 173.416(b)**] If Type B, NRC Certificate of Compliance granted before shipment or shipper is registered as a user of the Type B package? VDH-approved QA program? [**12VAC5-481-3130**]
 - 2. Package performance test records on file? [**49 CFR 173.415**]
 - 3. Special form sources documentation? [**49 CFR 173.476(a)**]
 - 4. Package has 2 labels (ex. Yellow-II) with TI, Nuclide, Activity, and Hazard Class? [**49 CFR 172.403; 49 CFR 173.441**]

5. Package properly marked? [**49 CFR 172.301; 49 CFR 172.304; 49 CFR 172.310; 49 CFR 172.324**]
6. Package closed and sealed during transport? [**49 CFR 173.475(f)**]
7. Shipping papers prepared, used, and maintained? [**49 CFR 172.200(a)**]
8. Shipping papers contain proper entries? {Shipping name, Hazard Class, Identification Number (UN Number), Total Quantity, Package Type, Nuclide, RQ, Radioactive Material, Physical and Chemical Form, Activity (SI units required), Category of Label, TI, Shipper's Name, Certification and Signature, Emergency Response Phone Number, Cargo Aircraft Only (If applicable)} [**49 CFR 172.200; 49 CFR 172.201; 49 CFR 172.202; 49 CFR 172.203; 49 CFR 172.204; 49 CFR 172.604**]
9. Secured against movement? [**49 CFR 177.834**]
10. Placarded on vehicle, if needed? [**49 CFR 172.504**]
11. Proper overpacks, if used? [**49 CFR 173.25**]
12. Any incidents reported to DOT? [**49 CFR 171.15; 49 CFR 171.16**]
13. Irradiators manufactured before 1966
 - a. Where any shipped?
 - b. Were VDH and DOT exemptions, if needed, received in advance?

Auditor's Independent Survey Measurements (If Made)

- A. Describe the type, location, and results of measurements.
- B. Do any radiation levels exceed regulatory limits?

Notifications and Reports

- A. Was any radioactive material lost or stolen? Were reports made?
[12VAC5-481-1090]
- B. Did any reportable incidents occur? Were reports made? [12VAC5-481-1090, 12VAC5-481-1100, 12VAC5-481-1110, 12VAC5-481-1150]
- C. Did any overexposures and high radiation levels occur? Reported?
[12VAC5-481-1100, 12VAC5-481-1110]
- D. If any events (as described in 1 through 3 above) did occur, what was root cause? Were corrective actions appropriate?
- E. Is the licensee aware of 24-hr VDH emergency telephone number [(804) 674-2400 or (800) 468-8892]?

Posting and Labeling

- A. VDH Form, 'Notice to Employees' posted? [12VAC5-481-2260 C]
- B. 12VAC5-481 'Virginia Radiation Protection Regulations', license documents posted or a notice posted? [12VAC5-481-2260 A]
- C. Other posting and labeling? [12VAC5-481-850, 12VA5-481-860, 12VAC5-481-880]

Record Keeping for Decommissioning

- A. Records kept of information important to decommissioning? [12VAC5-481-450 C]
- B. Records include all information outlined in 12VAC5-481-450 C?

Bulletins and Information Notices

- A. Agency Bulletins and/or Information Notices received?
- B. Appropriate training and action taken in response?

Special License Conditions or Issues

- A. Did auditor review any special license conditions?
- B. Did auditor review any other issues (e.g., non-routine maintenance)?

Deficiencies Identified in Audit; Corrective Actions

- A. Summarize problems/deficiencies identified during audit.
- B. If problems/deficiencies identified in this audit, describe corrective actions planned or taken. Include date(s) when corrective actions are implemented.
- C. Provide any other recommendations for improvement.

Evaluation of Other factors

- A. Senior licensee management is appropriately involved with the radiation protection program and/or Radiation Safety Officer (RSO) oversight?
- B. RSO has sufficient time to perform his/her radiation safety duties?
- C. Licensee has sufficient staff to support the radiation protection program?

Appendix K

Radiation Monitoring Instrument Specifications and Survey Instrument Calibration Program

Survey Instrument Calibration Program

Instrument(s) used with moving-source gamma irradiators must meet the following criteria:

- The instrument is a survey meter capable of detecting gamma radiation of more than 5×10^{-5} coulombs/kilogram (C/kg) (or up to several hundred milliroentgens (mR)) per hour which is:
 - In the licensee's possession
 - Checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation
 - Calibrated with a source of radiation annually and after any servicing or repair (other than a simple battery exchange), ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than $\pm 20\%$. Calibrations must be performed by the instrument manufacturer or a person specifically authorized by VDH, the NRC, or another Agreement State.

OR

- The instrument is a room monitor which:
 - Is in the licensee's possession
 - Is checked with a source of radiation at the beginning of each day of use to ensure that it will respond accurately to radiation and alarm at 0.02 mSv (2 mrem) per hour
 - Activates a visible and audible alarm when radiation levels exceed 0.02 mSv (2 mrem) per hour
 - Is positioned so it will detect any radiation escaping from the irradiator door yet still be visible to the irradiator operator when using the irradiator.

Instrument(s) used with fixed-source gamma irradiators (or beta irradiators) are:

- A survey meter capable of detecting gamma radiation (or beta radiation, as appropriate)
- In the licensee's possession or readily accessible in the event of an accident or malfunction which could reduce the shielding for the sealed source(s)
- Checked with a source of radiation at the beginning of each day of use to ensure that it will respond consistently to radiation
- Calibrated with a source of radiation annually and after any servicing or repair (other than a simple battery exchange), to ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than $\pm 20\%$. Calibrations must be performed by the instrument manufacturer or a person specifically authorized by VDH, the NRC or another Agreement State.

Training

Before allowing an individual to perform survey instrument calibrations, the RSO will ensure that the individual has sufficient classroom and on-the-job training to show competency in performing independent survey instrument calibrations.

Classroom training may be in the form of lecture, videotape, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job training consists of:

- Observing authorized personnel performing survey instrument calibration
- Conducting survey meter calibrations under the supervision and in the physical presence of an individual authorized to perform calibrations.

Facilities and Equipment

- To reduce doses received by individuals not calibrating instruments, calibrations will be conducted in an isolated area of the facility or at times when no one else is present
- Individuals conducting calibrations will wear assigned dosimetry
- Individuals conducting calibrations will use a calibrated and operable survey instrument to ensure that unexpected changes in exposure rates are identified and corrected.

Procedures for Calibrating Survey Instruments for Gamma Detection

- A radioactive sealed source(s) used for calibrating survey instruments will:
 - Approximate a point source
 - Have its apparent source activity or the exposure rate at a given distance traceable by documented measurements to a standard certified to be within $\pm 5\%$ accuracy by NIST
 - Approximately the same photon energy (Cs-137, Co-60) as the environment in which the calibrated device will be employed
 - Be strong enough to give an exposure rate of at least 7.7×10^{-6} C/kg/hr (or 30 mR/hr) at 100 cm [e.g., 3.1 GBq (85 mCi) of Cs-137) or 7.8×10^2 MBq (21 mCi) of Co-60].
- The inverse square and radioactive decay laws must be used to correct changes in exposure rate due to changes in distance or source decay.
- A record must be made of each survey meter calibration and retained for 3 years after each record is made (**12VAC5-481-1000**)
- A single point on a survey meter scale may be considered satisfactorily calibrated if the indicated exposure rate differs from the calculated exposure rate by less than $\pm 20\%$

- The three kinds of scales frequently used on radiation survey meters are calibrated either as described in ANSI N323A-1996, “*American National Standard Radiation Protection Instrumentation Test and Calibration- Portable Survey Instruments*”, or as follows:
 - Meters on which the user selects a linear scale must be calibrated at not fewer than two points on each scale. The points will be at approximately 1/3 and 2/3 of the decade.
 - Meters that have a multidecade logarithmic scale must be calibrated at one point (at the least) on each decade and not fewer than two points on one of the decades. Those points will be approximately 1/3 and 2/3 of the decade
 - Meters that have an automatically ranging digital display device for indicating exposure rates must be calibrated at one point (at the least) on each decade and at no fewer than two points on one of the decades. Those points will be approximately 1/3 and 2/3 of the decade.

- Readings above 2.58×10^{-4} C/kg/hr (1000 mR/hr) need not be calibrated. However, such scales should be checked for operation and approximately correct response.

- Survey meter calibration reports will indicate the procedure used and the data obtained. The description of the calibration will include:
 - The owner or user of the instrument
 - A description of the instrument including the manufacturer’s name, model number, serial number, and type of detector
 - A description of the calibration source, including the exposure rate at a specified distance on a specified date, and the calibration procedure
 - For each calibration point, the calculated exposure rate, the indicated exposure rate, the deduced correction factor (the calculated exposure rate divided by the indicated exposure rate), and the scale selected on the instrument
 - The exposure reading indicated with the instrument in the ‘battery check’ mode (if available on the instrument)
 - For instruments with external detectors, the angle between the radiation flux field and the detector (i.e., parallel or perpendicular)
 - For instruments with internal detectors, the angel between radiation flux field and a specified surface of the instrument
 - For detectors with removable shielding, an indication whether the shielding was in place or removed during the calibration procedure
 - The exposure rate from a check source, if used
 - The person’s name who performed the calibration and date it was performed

- The following information will be attached to the instrument as a calibration sticker or tag:
 - The source that was used to calibrate the instrument
 - The proper deflection in the battery check mode (unless this is clearly indicated on the instrument)
 - For each scale or decade not calibrated, an indication that the scale or decade was checked on for function but not calibrated
 - The date of calibration and the next calibration due date
 - The apparent exposure rate from the check source, if used.

References: Detailed information about survey instrument calibration may be obtained by referring to ANSI N323A-1996, *"American National Standard Radiation Protection Instrumentation Test and Calibration - Portable Survey Instruments"*. Copies may be ordered electronically at <http://www.ansi.org> or by writing to: ANSI, 1430 Broadway, New York, NY 10018. See Section 8.10.2 and Appendix J of NRC NUREG 1556 Vol. 18 *"Program Specific Guidance about Service Provider Licenses"*, and is available electronically at NRC's web site, <http://www.nrc.gov>.

Appendix L

Guidance for Demonstrating That Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Limits

Guidance for Demonstrating That Unmonitored Individuals Are Not Likely to Exceed 10 Percent of the Allowable Limits

Dosimetry is required for individuals likely to receive, in 1 year from sources external to the body, a dose in excess of 10% of the applicable regulatory limits in **12VAC5-481-640**, **12VAC5-481-700**, and **12VAC5-481-710**. To demonstrate that dosimetry is not required, a licensee needs to perform a prospective evaluation to demonstrate that its workers are not likely to exceed 10% of the applicable annual limits.

The most common way that individuals might exceed 10% of the applicable limits is by performing frequent routine maintenance on the irradiator. However, for most new irradiators even these activities result in the individual's receiving minimal doses. Before allowing workers to perform these tasks, a licensee will need to evaluate the doses which its workers might receive to assess whether dosimetry is required; this is a prospective evaluation.

Example

The following is an example of an estimate of the dose received by the extremities and whole body of a person performing routine maintenance (cleaning and lubrication) on a self-shielded irradiator rotating drawer drive chain. The estimate is based on observations of individuals performing the recommended procedure according to good radiation safety practices. The manufacturer can provide the following types of information:

- Time needed to perform the entire procedure (e.g., 20 min)
- Extremity dose rate received by an individual, associated with the shielded source (e.g., 0.02 mSv/hr [2 mrem/hr] at contact with the shield)
- Time the hands were exposed to the shielded source (e.g., 3 min)
- Whole body dose rate received by an individual, associated with the shielded source (e.g., 0.01 mSv/hr [1 mrem/hr] at contact with the shield)
- Time the whole body is exposed to the shielded source (e.g., 20 min)

From this information, an estimate of the doses that the individual performing this procedure could receive is as follows:

- 0.001 mSv [0.1 mrem] to the hands
- Less than 0.0033 mSv [0.33 mrem] TEDE (whole body).

The applicable TEDE (whole body) limit is 50 mSv (5 rems) per year and 10% of that value is 5 mSv (500 mrem) per year. If one of these procedures delivers 0.0033 mSv (0.33 mrem), then an individual could perform 1,515 of these procedures each year and remain within 10% of the applicable limit.

The applicable shallow-dose equivalent (SDE) (extremities) is 500 mSv (50 rems) per year and 10% of that value is 50 mSv (5 rems or 5000 mrem) per year. If one of these procedures delivers 0.001

mSv (0.1 mrem), then an individual could perform 50,000 of these procedures each year and remain within 10% of the applicable limit.

Based on the above specific situation, no dosimetry is required if a worker performs fewer than 1,515 routine maintenance procedures per year.

Guidance to Licensees

Licensees who wish to demonstrate that they are **not** required to provide dosimetry to their workers need to perform prospective evaluations similar to that shown in the example above. The expected dose rates, times, and distances used in the above example may **not** be appropriate to individual licensee situations. In their evaluations, licensees need to use information appropriate to the type(s) of self-shielded irradiator(s) they intend to use; this information is generally available from the irradiator manufacturer (or distributor) or the SSDR Certificate maintained by VDH, the NRC and other Agreement States.

Table 8 may be helpful in performing a prospective evaluation.

<p>Note: For ease of use by most irradiator licensees, this table uses conventional units. The conversion to SI units is: 1 mrem = 0.01 mSv.</p>

Licensees should review evaluations periodically and revise them as needed. Licensees need to check assumptions used in their evaluations to ensure that they continue to be up-to-date and accurate. For example, if workers become lax in following good radiation safety practices, perform the task more slowly than estimated, work with new irradiators containing sources of different activities or radionuclides, or use modified procedures, the licensee would need to conduct a new evaluation.

Table 8. Dosimetry Evaluation

Dosimetry Evaluation for :		Model:	Self-Shielded Irradiator	
A.	Time needed to perform the entire routine maintenance procedure.		____ (minutes/60)	____ hour
B.	Expected whole body dose rate received by the individual, determined using exposure rates measured on contact with the irradiator while the sealed source is in the shielded position.		____ mrem/hr	
C.	Time the hands were exposed to the unshielded source.		____ (minutes/60)	____ hour
D.	Expected extremity dose rate received by the individual, determined using exposure rates measured at the typical distance that the hands would be from the sealed source during the routine maintenance procedure.		____ mrem/hr	

Formula: (____ # hours in Row A) x (____ mrem/hr in Row B) = (____ mrem per routine procedure) x (____ # of routine maintenance procedure each year) = ____ mrem * Whole Body Dose

Formula: (____ # hours in Row C) x (____ mrem/hr in Row D) = (____ mrem per routine procedure) x (____ # of routine maintenance procedures each year) = ____ mrem ** Extremity Dose

* Expected Whole Body Doses less than 500 mrem requires no dosimetry

** Expected Extremity Doses less than 5000 mrem requires no dosimetry

Appendix M

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Guidance for Demonstrating That Individual Members of the Public Will Not Receive Doses Exceeding the Allowable Limits

Licensees must ensure that:

- The radiation dose received by individual members of the public does not exceed 1 mSv (100 mrem) in one calendar year resulting from the licensee's possession and/or use of licensed materials.

Members of the public include persons who live, work, or may be near locations where self-shielded irradiator devices are used or stored and employees whose assigned duties do not include the use of licensed materials and who work in the vicinity where irradiators are used or stored.

- The radiation dose in unrestricted areas does not exceed 0.02 mSv (2 mrem) in any one hour.

Typical unrestricted areas may include offices, shops, laboratories, areas outside buildings, property, and non-radioactive equipment storage areas. The licensee does not control access to these areas for purposes of controlling exposure to radiation or radioactive materials. However, the licensee may control access to these areas for other reasons such as security.

Licensees must show compliance with both portions of the regulation. For areas around self-shielded irradiator facilities, calculations or a combination of calculations and measurements (e.g., using an environmental TLD) are often used to prove compliance.

Calculation Method

The calculation method takes a tiered approach, going through a three-part process starting with a worst case situation and moving toward more realistic situations. It makes the following simplifications: (1) each irradiator is a point source; (2) typical radiation levels encountered when the source is in the shielded position are taken from either the SSDR Certificate, ANSI N433.1, (7) *"Safe Design and Use of Self-Contained, Dry Source Storage Gamma Irradiator (Category I)"*, or the manufacturer's (or distributor's) literature; and (3) no credit is taken for any shielding found between the irradiator and the unrestricted areas.

Note: Copies may be ordered electronically at <http://www.ansi.org> or by writing to ANSI, 1430 Broadway, New York, NY 10018. Copies are also available from the NTIS, 5285 Port Royal Road, Springfield, VA 22161 1-800-553-6847.

Part 1 of the calculation method is simple but conservative. It assumes that an affected member of the public is present 24 hours a day and uses only the inverse square law to determine if the distance between the irradiator and the affected member of the public is sufficient to show compliance with the public dose limits. **Part 2** considers not only distance, but also the time that the affected member of the public is actually in the area under consideration. **Part 3** considers the distance, the portion of time and dose rate while the sample is in transit, the portion of time and dose rate while the sample is not in transit, and the portion of time that the affected member of the public is present. Using this approach, licensees make only those calculations that are needed to demonstrate compliance. In many cases licensees will need to use the calculation method through **Part 1** or **Part 2**. The results of these calculations typically result in higher radiation levels than would exist at typical facilities, but provide a conservative method for estimating doses which could be received.

Example 1

To better understand the calculation method, we will examine Bugs-Away, Inc., a self-shielded irradiator licensee. Yesterday, the company's president noted that the new irradiator area is close to his secretary's desk and he asked Joe, the Radiation Safety Officer (RSO), to determine if the company is complying with **12VAC5-481-720**.

The secretary's desk is near the wall separating the reception area from the designated, locked self-shielded irradiator room where the company has located its irradiator. Joe measures the distance from the self-shielded irradiator to the wall and assumes that the irradiator would have the maximum dose rate allowed under ANSI N433.1 of 10 mrem per hour at one meter. This is the maximum dose rate permitted while the sample is in transit (i.e., moving into or out of the irradiation position). Joe uses this information to determine the dose rate in mrem/hr at a specified distance from the irradiator determined to be 10 mrem/hr at 1 meter (3.28 ft). He also determines that the secretary's chair is 15 feet from the irradiator.

Example 1: Part 1

Joe's first thought is that the distance between the irradiator and the secretary's chair may be sufficient to show compliance with the regulation in **12VAC5-481-720**. So, taking a worst case approach, he assumes: 1) the self-shielded irradiator is constantly present (i.e., 24 hr/d) with the samples constantly in transit, and 2) the secretary is constantly sitting in the desk chair (i.e., 24 hr/d). Joe proceeds to calculate the dose she might receive hourly and yearly from the self-shielded irradiator as shown in **Table 9** below.

Table 9. Calculation Method, Part 1: Hourly and Annual Dose Received from Self-Shielded Irradiator

Step No.	Description	Input Data	Result
1	Dose received in an hour at known distance from irradiator (e.g., from ANSI N433.1), in mrem/hr	10	10
2	Square of the distance (ft) at which the Step 1 rate was measured, in ft ²	(3.28) ²	10.8
3	Square of the distance (ft) from the irradiator to the secretary's desk in an unrestricted area in ft ²	(15.0) ²	225
4	Multiply the results of Step 1 by the results of Step 2 (this is an intermediate result)	10 x 10.8	108 (rounded to 110)
5	Divide the results of Step 4 by the result of Step 3 to calculate the dose received by an individual at the secretary's desk, HOURLY DOSE RECEIVED FROM SELF-SHIELDED IRRADIATOR , in mrem in an hour	110/225	0.48
6	Multiply the result of Step 5 by 24 hr/d x 366 (leap year) d/yr = MAXIMUM ANNUAL DOSE RECEIVED FROM SELF-SHIELDED IRRADIATOR , in mrem in a year	0.48 x 24 x 366	4200

Note: The result in Step 5 demonstrates compliance with the 2 mrem in any one hour limit. Reevaluate if assumption change. If the result in Step 6 exceeds 100 mrem/yr, proceed to Part 2 of the calculation method.

At this point, Joe is pleased to see that the total dose that an individual could receive in any one hour is only 0.48 mrem, but notes that an individual could receive a dose of 4,200 mrem in a year, much higher than the 100 mrem limit.

Example 1: Part 2

Joe reviews his assumptions and recognizes that the secretary is not at the desk 24 hr/d. He decides to make a realistic estimate of the number of hours the secretary sits in the chair at the desk, keeping his other assumptions constant (i.e., the self-shielded irradiator is constantly present (i.e., 24 hr/d) with the samples constantly in transit). He then recalculates the annual dose received.

Table 10. Calculation Method, Part 2: Annual Dose Received from Self-Shielded Irradiator

Step No.	Description	Result
7	A. Average number of hours per day that individual spends in area of concern (e.g., secretary sits at desk 5 hr/d; the remainder of the day the secretary is away from the desk area copying, filing, etc.)	5.0
	B. Average number of days per week in area (e.g., secretary is part time and works 3 d/wk)	3.0
	C. Average number of weeks per year in area (e.g., secretary works all year)	52
8	Multiply the results of Step 7.A by the results of Step 7.B. by the results of Step 7.C. = AVERAGE NUMBER OF HOURS IN AREA OF CONCERN PER YEAR	$5.0 \times 3.0 \times 52 = \mathbf{780}$
9	Multiply the results in Step 5 by the results of Step 8 = ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATE OF TIME SPENT IN AREA OF CONCERN , in mrem in a year	$0.48 \times 780 = \mathbf{370}$

Note: If Step 9 exceeds 100 mrem in a year, proceed to Part 3 of the Calculation method.

Although Joe is pleased to note that the calculated annual dose received is significantly lower, he realizes it still exceeds the 100 mrem in a year limit.

Example 1: Part 3

Again, Joe reviews his assumptions and recognizes that the irradiator is not constantly in use nor is the sample continuously in transit during an irradiation cycle when the secretary is seated at the desk. As he examines the situation, he realizes he must take these factors into account.

First, he realizes that while the irradiator is in transit, the dose rate at 3.28 feet is 10; however, when it is idle or when a sample is irradiated, the dose rate at 3.28 feet is reduced to 2 mrem/hr. The maximum number of irradiations per hour is 5 with a 3 minute maximum irradiation time. The time the sample is in transit per irradiation cycle is also 0.2 minutes. Referring to previous information, he takes into account that the secretary's chair is 15 feet away from the irradiator and the secretary is present for 780 hours per year.

Table 11. Calculation Method, Part 3: Annual Dose Received from Irradiator

Step No.	Description	Result
18	[60 minus the input from Step 13 multiplied by (the input from Step 14 plus the input from Step 15) divided by 60 = $[60. - 5.0 \times (3.0 + 0.20)] / 60. = [60. - 16.] / 60 =$ FRACTION OF TIME THE IRRADIATOR IS IDLE	0.73
19	(The input from Step 13 multiplied by the input from Step 15) divided by 60 = $(5.0 \times 0.20) / 60 = 1/60 =$ FRACTION OF TIME THE SAMPLE IS IN TRANSIT	0.017
20	1.0 minus the result from Step 18 minus the result from Step 19 = $1 - 0.73 - 0.017 =$ FRACTION OF TIME THE IRRADIATOR IS IN USE	0.253
21	(The input from Step 10 multiplied by the result from Step 18) plus (the input from Step 11 multiplied by the result from Step 19) plus (the input from Step 12 multiplied by the result from Step 20) = $(2.0 \times 0.73) + (10. \times 0.017) + (2.0 \times 0.253) = 1.46 + 0.17 + 0.506 =$ AVERAGE DOSE RATE ENCOUNTERED AT 3.28 FEET FROM THE IRRADIATOR , in mrem in an hour	2.136
22	The result from Step 21 multiplied by (3.28 squared divided by the input from Step 16 squared) = $2.136 \times (3.28^2 / 15^2) = 2.136 \times (10.8/225) =$ AVERAGE DOSE RATE ENCOUNTERED BY THE SECRETARY , in mrem per hour	0.10
23	The result from Step 22 multiplied by the input from Step 17 = $780 \times 0.10 =$ ANNUAL DOSE RECEIVED FROM IRRADIATOR CONSIDERING REALISTIC ESTIMATES FOR TIME SPENT IN AREA OF CONCERN, DOSE RATES, AND IRRADIATOR USAGE , in mrem in a year	78.

Note: If the result in Step 23 is greater than 100 mrem/yr, the licensee must take corrective actions

Joe is glad to see that the results in Step 23 show compliance with the 100 mrem in a year limit. Had the result in Step 23 been higher than 100 mrem in a year, then Joe could have done one or more of the following:

- Consider whether the assumptions used to determine occupancy are accurate, revise the assumptions as needed, and recalculate using the new assumptions
- Calculate the effect of any shielding located between the irradiator area and the secretarial workstation -- such calculation is beyond the scope of this Appendix
- Take corrective action (e.g., move irradiator within the use area, move the use area, move the secretarial workstation) and perform new calculations to demonstrate compliance

- Designate the area outside the use area as a restricted area and the secretary as an occupationally exposed individual. This would require controlling access to the area for purposes of radiation protection and training the secretary.

Note: National Council on Radiation Protection and Measurements (NCRP) Report No. 49, "*Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV*", contains helpful information. It is available from NCRP, 7910 Woodmont Avenue, Suite 800, Bethesda, Maryland 20814. NCRP's telephone numbers are: (301) 657-2652 or 1-800-229-2652.

Note that in the example, Joe evaluated the unrestricted area outside only one wall of the irradiator area. Licensees also need to make similar evaluations for other unrestricted areas and to keep in mind the ALARA principle, taking reasonable steps to keep radiation dose received below regulatory requirements. In addition, licensees need to be alert to changes in situations (e.g., moving the self-shielded irradiator closer to the secretarial workstation, adding a second irradiator, changing the secretary to a full-time worker, or changing the estimate of the portion of time spent at the desk) and to perform additional evaluations, as needed.

RECORDKEEPING: 12VAC5-481-1050 requires licensees to maintain records demonstrating compliance with the dose limits for individual members of the public.

Combination Measurement-Calculation Method

This method, which allows the licensee to take credit for shielding between the irradiator and the area in question, begins by measuring radiation levels in the areas, as opposed to using ANSI-N433.1 or manufacturer- (or distributor-) supplied rates at a specified distance from each irradiator. These measurements must be made with calibrated survey meters sufficiently sensitive to measure background levels of radiation. However, licensees must exercise caution when making these measurements, and they must use currently calibrated radiation survey instruments. A maximum dose of 1 mSv (100 mrem) received by an individual over a period of 2080 hours (i.e., a 'work year' of 40 hr/wk for 52 wk/yr) is equal to less than 0.5 microsievert (0.05 mrem) per hour.

This rate is well below the minimum sensitivity of most commonly available G-M survey instruments.

Instruments used to make measurements for calculations must be sufficiently sensitive. An instrument equipped with a scintillation-type detector (e.g., NaI(Tl)) or a micro-R meter used in making very low gamma radiation measurements should be adequate.

Licensees may also choose to use environmental TLDs (see note) in unrestricted areas next to the irradiator area for monitoring. This direct measurement method would provide a definitive measurement of actual radiation levels in unrestricted areas without any restrictive assumptions. Records of these measurements can then be evaluated to ensure that rates in unrestricted areas do not exceed the 1 mSv/yr (100 mrem/yr) limit.

Note: TLDs used for personnel monitoring (e.g., LiF) may not have sufficient sensitivity for this purpose. Generally, the minimum reportable dose received is 0.1 mSv (10 mrem). Suppose a TLD monitors dose received and is changed once a month. If the measurements are at the minimum reportable level, the annual dose received could have been about 1.2 mSv (120 mrem), a value in excess of the 1 mSv/yr (100 mrem/yr) limit. If licensees use TLDs to evaluate compliance with the public dose limits, they should consult with their TLD supplier and choose more sensitive TLDs, such as those containing CaF₂ that are used for environmental monitoring.

Example 2

As in Example 1, Joe is the RSO for Bugs-Away, Inc., a self-shielded irradiator licensee. The company has one irradiator in a designated, locked area that adjoins an unrestricted area where a secretarial workstation is located. Refer to previous Example 1 for additional information. Joe wants to see if the company complies with the public dose limits at the secretarial station.

Joe placed an environmental TLD badge in the secretarial work space for 30 days. The TLD processor sent Joe a report indicating the TLD received 100 mrem.

Table 12. Combination Measurement-Calculation Method

Step No.	Description	Input Data and Results
Part 1		
1	Dose received by TLD, in mrem	100
2	Total hours TLD exposed	24 hr/d x 30 d/mo = 720
3	Divide the results of Step 1 by the results of Step 2 = HOURLY DOSE RECEIVED , in mrem in an hour	100/720 = 0.14
4	Multiply the results of Step 3 by 366 d/yr [leap year] x 24 hr/d = 8784 hours in one year = MAXIMUM ANNUAL DOSE RECEIVED FROM IRRADIATOR , in mrem in a year	366 x 24 x 0.14 = 8784 x 0.14 = 1230

Note: For the conditions described above, Step 3 indicates that the dose received in any one hour is less than the 2 mrem in any one hour limit. However, if there are any changes, then the licensee would need to reevaluate the potential doses which could be received in any one hour. Step 4 indicates that the annual dose received would be much greater than the 100 mrem in a year allowed by the regulations

Part 2

At this point Joe can adjust for a realistic estimate of the time the secretary spends in the area as he did in Part 2 of Example 1.

Part 3

If the results of Joe's evaluation in Part 2 show that the annual dose received in a year exceeds 100 mrem, then he may have to consider moving the self-shielded irradiator or the secretary's desk, or adding shielding to the wall.

Appendix N

Typical Agency Incident Notifications Required for Self-Shielded Irradiator Licensees

VDH Incident Notifications

Table 13. Typical VDH Incident Notifications Required for Self-Shielded Irradiator Licensees

Event	Telephone Notification	Written Report	Rule Requirement
Theft or lost of material	Immediate	30 days	12VAC5-481-1090
Whole body dose greater than 0.25 Sv (25 rems)	Immediate	30 days	12VAC5-481-1100
Extremity dose greater than 2.5 Sv (25 rems)	Immediate	30 days	12VAC5-481-1100
Whole body dose greater than 0.05 Sv (5 rems) in 24 hours	24 hours	30 days	12VAC5-481-1100
Extremity dose greater than 0.5 Sv (50 rems) in 24 hours	24 hours	30 days	12VAC5-481-1100
Whole body dose greater than 0.05 Sv (5 rems)	None	30 days	12VAC5-481-1110
Dose to individual member of public greater than 1 mSv (100 mrem)	None	30 days	12VAC5-481-1110
Filing petition for bankruptcy under 11 U.S.C.	None	Immediately after filing petition	12VAC5-481-500 E & F
Expiration of license	None	60 days	12VAC5-481-510 D
Decision to permanently cease license activities at entire site	None	30 days	12VAC5-481-510 D
Decision to permanently cease licensed activities in any separate building or outdoor area that is unsuitable for release for unrestricted use.	None	60 days	12VAC5-481-510 D
No principal activities conducted for 24 months at the entire site	None	60 days	12VAC5-481-510 D
No principal activities conducted for 24 months in any separate building or outdoor area that is unsuitable for release	None	60 days	12VAC5-481-510 D

Event	Telephone Notification	Written Report	Rule Requirement
Event that prevents immediate protective actions necessary to avoid exposure to radioactive materials that could exceed regulatory limits	Immediate	30 days	12VAC5-481-1100, 12VAC5-481-1110
Equipment is disabled or fails to function as designed when required to prevent radiation exposure in excess of regulatory limits	24 hours	30 days	12VAC5-481-1110
Unplanned fire or explosion that affects the integrity of any licensed material or device, container, or equipment with licensed material	24 hours	30 days	12VAC5-481-1110

Note: Telephone notifications shall be made to the agency at (804) 864-8150 (during office hours) or (804) 674-2400 or (800) 468-8892 (24-hour emergency number) if an emergency. Identify emergency as radiological.

Appendix O

Information for Applicants to Consider When Developing Operating and Emergency Procedures for Self-Shielded Irradiators

Elements of Operating and Emergency Procedures Applicable to All Types of Self-Shielded Irradiators

- Analyze each type of material to be placed in the irradiator to ensure that it is comparable with the irradiator's design or to determine whether special procedures in addition to those given by the manufacturer (or distributor) are required to ensure the safe operation of the irradiator.
- Prepare model-specific instructions for routine inspections, test procedures, and maintenance to ensure that all interlocks, devices, and components critical to the safe operation of the irradiator are functioning properly. (Prohibited actions such as changing the safety control system or removing the source should be stated.)
- Develop methods to maintain accountability (e.g., logbook to record irradiator use) and to ensure that only authorized persons will use or have access to the irradiator (e.g., control access to the irradiator's keys or control access to the area where the irradiator is located).
- Define steps to take to keep radiation exposures ALARA
- For each model irradiator, define step-by-step procedures on how to operate the irradiator and how to perform routine maintenance. Information may be extracted from the manufacturer's (or distributor's) manual.

Specific Operating Procedures Applicable to Moving-Source Irradiators

- The irradiator should not be used unless the licensee provides a calibrated and operable radiation survey meter or a room monitor for use with the irradiator.
- The irradiator door should not be opened until the operator has checked visual indicators to verify that the source has returned to its safe storage position.
- Each room monitor should:
 - Be operable at all times when the irradiator is in use
 - Activate a visible and audible alarm when radiation levels exceed 0.02 mSv (2 mrem) per hour
 - Be located to detect any radiation escaping from the irradiator door
 - Be located so that it is visible to the irradiator user when next to the irradiator
- If a room monitor is not installed, a survey meter should be used to:
 - Determine the radiation level at the irradiator door when the door is closed
 - Check for any increase in radiation levels each time the irradiator door is opened. In conducting such checks, operators should position themselves to minimize exposure to any radiation escaping from the open door.

- If abnormal radiation levels or any malfunction of the irradiator are detected at any time, the licensee should stop using the irradiator, restrict access to the area housing the irradiator, immediately notify the RSO, and determine if a report to the agency is required.
- The licensee should not attempt to repair or authorize others to attempt to repair the irradiator except as specifically authorized in a license issued by VDH.

Elements of Emergency Procedures Applicable to All types of Self-Shielded Irradiators

- Leave the irradiator area (to reduce radiation exposure).
- Control access to the area (e.g., lock door).
- Contact responsible individuals (e.g., names, phone numbers of RSO, irradiator manufacturer (or distributor), emergency response organizations such as fire department, agency).
- Take additional steps, dependent on the specific situations (e.g., surveys).
- As appropriate, require timely reporting to the agency

Changes to Operating and Emergency Procedures Without a License Amendment

Licensees may change their operating and emergency procedures without amending their license if:

- The changes are reviewed and approved by licensee management and the RSO
- Affected licensee staff are trained in the procedures before they are implemented
- The changes are consistent with applicable license conditions and the procedures or commitments submitted in the license application
- The changes do not degrade the safety of the program.

Copies of operating and emergency procedures should be provided to all users. Post a current copy at each irradiator's control panel. If posting the operating procedures is not practicable, post a notice describing the document(s) and where it may be examined.

Appendix P

Leak Test Program

Leak Test Program

Training

Before allowing an individual to perform leak testing, the RSO will ensure that he or she has sufficient classroom and on-the-job training to show competency in performing leak tests independently.

Classroom training may be in the form of lecture, videotape, hands-on, or self-study and will cover the following subject areas:

- Principles and practices of radiation protection
- Radioactivity measurements, monitoring techniques, and using instruments
- Mathematics and calculations basic to using and measuring radioactivity
- Biological effects of radiation.

Appropriate on-the-job-training consists of:

- Observing authorized personnel collecting and analyzing leak test samples .
- Collecting and analyzing leak test samples under the supervision and in the physical presence of an individual authorized to perform leak tests.

Facilities and Equipment

- To ensure achieving the required sensitivity of measurements, leak tests will be analyzed in a low-background area.
- Individuals conducting leak tests will use a calibrated and operable survey instrument to check leak test samples for gross contamination before they are analyzed. If the sensitivity of the counting system is unknown, the minimum detectable activity (MDA) needs to be determined. The MDA may be determined using the following formula:

$$MDA = \frac{2.71 + 4.65\sqrt{B_R \times t}}{t \times E} = \text{Minimum Detectable Activity}$$

where:

MDA	=	activity level in disintegrations per minute
B _R	=	background rate in counts per minute
t	=	counting time in minutes
E	=	detector efficiency in counts per disintegrations

For example:

B _R	=	200 counts per minute
E	=	0.1 counts per disintegration (10% efficient)
t	=	2 minutes

$$\begin{aligned}
 MDA &= \frac{2.71 + 4.65\sqrt{(200 \times 2)}}{2 \times 0.1} = \frac{2.71 + 4.65\sqrt{(400)}}{0.2} \\
 &= \frac{2.71 + 4.65(20)}{0.2} = \frac{2.71 + 93}{0.2} = \frac{95.71}{0.2} \\
 &= \frac{59 \text{ disintegrations}}{\text{minute}} \\
 \text{becquerels (Bq)} &= \frac{1 \text{ disintegration}}{\text{second}} \\
 \text{Bq} &= \frac{59 \text{ disintegrations}}{\text{minutes}} \times \frac{\text{minute}}{60 \text{ seconds}} = 0.98 = 1 \text{ Bq}
 \end{aligned}$$

- A NaI(Tl) well counter system with a single or multi-channel analyzer will be used to count samples from irradiators containing gamma-emitters (e.g., Cs-137, Co-60).
- A liquid scintillation or gas-flow proportional counting system will be used to count samples from irradiators containing beta-emitters (e.g., Sr-90).

Frequency for Conducting Leak Tests of Sealed Sources

- Leak tests will be conducted at the frequency specified in the respective SSDR Certificate.

Procedure for Performing Leak Testing and Analysis

- For each source to be tested, list identifying information such as self-shielded irradiator serial number, radionuclide, activity.
- If available, use a survey meter to monitor exposure.
- Prepare a separate wipe sample (e.g., cotton swab or filter paper) for each source.
- Number each wipe to correlate with identifying information for each source.
- Wipe the most accessible area where contamination would accumulate if the sealed source were leaking.
- Select an instrument that is sensitive enough to detect 185 Bq (0.005 microcurie) of the radionuclide in the irradiator.

- Using the selected instrument, count and record background count rate.
- Check the instrument's counting efficiency using a standard source of the same radionuclide as the source being tested or one with similar energy characteristics. Accuracy of standards should be within $\pm 5\%$ of the stated value and traceable to primary radiation standards such as those maintained by NIST.
- Calculate efficiency.

For example:
$$\frac{[(\text{cpm from std}) - (\text{cpm from bkg})]}{\text{Activity of std in Bq}} = \text{efficiency in cpm/bq}$$

Where:

cpm	=	counts per minute
std	=	standard
bkg	=	background
Bq	=	Becquerel

- Count each wipe sample; determine net count rate
- For each sample, calculate and record estimated activity in Bq (or microcuries).

For example:
$$\frac{[(\text{cpm from wipe sample}) - (\text{cpm from bkg})]}{\text{Efficiency in cpm/Bq}} = \text{Bq on wipe sample}$$

- Sign and date the list of sources, date and calculations. Retain records for 5 years (12VAC5-481-1010).
- If the wipe test activity is 185 Bq (0.005 microcurie) or greater, notify the RSO, so that the source can be withdrawn from use and disposed of properly. Also notify the agency.

Reference: See Section 8.10.8 and Appendix O of NRC NUREG 1556 Vol. 18 “*Program Specific Guidance about Service Provider Licenses*”, and is available electronically at NRC’s web site, <http://www.nrc.gov>.

Appendix Q

Transportation

Part 1: Major DOT Regulations

The major areas in the DOT regulations that are most relevant for transportation of typical self-shielded irradiators that are shipped as Type A or Type B quantities are as follows:

- Table of Hazardous Materials and Special Provisions **49 CFR 172.101**, and App. A, Table 2: Hazardous materials table, list of hazardous substances and reportable quantities
- Shipping Papers **49 CFR 172.200-204**: general entries, description, additional description requirements, shipper's certification
- Package Markings **49 CFR 172.300, 49 CFR 172.301, 49 CFR 172.303, 49 CFR 172.304, 49 CFR 172.310, 49 CFR 172.324**: General marking requirements for non-bulk packagings, prohibited marking, marking requirements, radioactive material, hazardous substances in non-bulk packaging
- Package Labeling **49 CFR 172.400, 49 CFR 172.401, 49 CFR 172.403, 49 CFR 172.406, 49 CFR 172.407, 49 CFR 172.436, 49 CFR 172.438, 49 CFR 172.440**: General labeling requirements, prohibited labeling, radioactive materials, placement of labels, specifications for radioactive labels
- Placarding of Vehicles **49 CFR 172.500, 49 CFR 172.502, 49 CFR 172.504, 49 CFR 172.506, 49 CFR 172.516, 49 CFR 172.519, 49 CFR 172.556**: Applicability, prohibited and permissive placarding, general placarding requirements, providing and affixing placards: highway, visibility and display of placards, RADIOACTIVE placard
- Emergency Response Information, Subpart G, **49 CFR 172.600, 49 CFR 172.602, 49 CFR 172.604**: Applicability and general requirements, emergency response information, emergency response telephone number
- Training, Subpart H, **49 CFR 172.702, 49 CFR 172.704**: Applicability and responsibility for training and testing, training requirements
- Radiation Protection Program for Shippers and Carriers, Subpart I, **49 CFR 172.800**, etc.
- Shippers - General Requirements for Shipments and Packaging, Subpart I, **49 CFR 173.403, 49 CFR 173.410, 49 CFR 173.411, 49 CFR 173.412, 49 CFR 173.413, 49 CFR 173.415, 49 CFR 173.416, 49 CFR 173.433, 49 CFR 173.435, 49 CFR 173.441, 49 CFR 173.471, 49 CFR 173.475, 49 CFR 173.476**: Definitions, general design requirements, industrial packages, additional design requirements for Type A packages, requirements for Type B packages, authorized Type A packages, authorized Type B packages (including package certification requirements), requirement for determining A_1 and A_2 ..., table of A_1 and A_2 values for radionuclides, radiation level limit, requirements for U.S. NRC-approved packages (Type B), quality control requirements prior to each shipment..., approval of special form radioactive materials
- Carriage by Public Highway, **49 CFR 177.816, 49 CFR 177.817, 49 CFR 177.834(a), 49 CFR 177.842**: Driver training, shipping paper, general requirements (secured against movement), Class 7 (radioactive) material.

Part 2: Sample Bill of Lading

STRAIGHT BILL OF LADING ORIGINAL—NOT NEGOTIABLE

Shipper No _____
 Carrier No _____
 Date _____

Page 1 of 1

Name of carrier: SCAC

TO: Consignee Irradiator Maker, Inc. ** <small>On Collect on Delivery shipments, the letters "C.O.D." must appear before consignee's name or 35 (otherwise provided in item 430, Sec. 1)</small>		FROM: Shipper Irradiation Studies, Inc. **	
Street 4321 Broad Street **		Street 1234 A Street, NW **	
Destination Somewhere USA ** Zip Code 12345**		Origin Washington, DC 20001 **	

No. of Units & Container Type	HM	BASIC DESCRIPTION <small>Proper Shipping Name, Hazard Class, Identification Number (UN or NA), per 172.101, 172.202</small>	TOTAL QUANTITY <small>(Weight, Volume, Gallons, etc.)</small>	WEIGHT <small>(Subject to Correction)</small>	RATE	CHARGES <small>(For Carrier Use Only)</small>
1	RQ	Radioactive material, special form, n.o.s., 7, UN2974 100 TBq Cs-137 **	100 TBq **			
		RADIOACTIVE - YELLOW (I) ** TI = 0.4 ** USA/1234/B(U) Type B Container ** Emergency Response Telephone No. 1-800-000-0000 (24 hr/d) **				
		** SUBSTITUTE APPROPRIATE INFORMATION FOR YOUR SHIPMENT				

PLACARDS TENDERED: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		REMIT C.O.D. TO: ADDRESS	C.O.D. FEE: PREPAID <input type="checkbox"/> COLLECT <input type="checkbox"/> \$
<small>Note: Where the rate is dependent on value, shippers are required to state specifically in writing the agreed or declared value of the property. The agreed or declared value of the property is hereby specifically stated by the shipper to be not exceeding:</small>		COD Amt: \$	TOTAL CHARGES: \$
<small>I hereby declare that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packaged, marked and labeled and are in all respects in proper condition for transport by a rail or highway in those COUNTRY MODES APPLICABLE TO MODE OF TRANSPORT according to applicable international and national governmental regulations.</small> <i>John J. Jones</i> Signature		<small>Subject to Section 7 of the conditions, if the shipment is to be delivered to the consignee without recourse on the consignor, the consignor shall sign the following statement: The carrier shall not make delivery of the shipment without payment of freight and all other lawful charges.</small>	FREIGHT CHARGES Freight prepaid <input type="checkbox"/> Check box if shipment is to be collected <input type="checkbox"/>

RECEIVED: Subject to the classifications and identity used herein in effect on the date of the issue of this Bill of Lading, the property described above in accordance with the terms and conditions and conditions of contents of packages (wherever marked, consigned) and delivered as indicated above which said carrier, the said carrier being understood throughout this contract as meaning any person or corporation in possession of the property under the contract, agrees to carry to its usual place of delivery at said destination, if on its route, otherwise to deliver to another carrier on the route to said destination. It is mutually agreed as to each carrier or all or any of said property over all or any portion of said route to destination and as to each party at any time interested in all or any said property that every service to be performed hereunder shall be subject to all the bill of lading terms and conditions in the governing classification of the date of shipment.
Shipper hereby certifies that he is familiar with all the bill of lading terms and conditions in the governing classification and the said terms and conditions are hereby agreed to by the shipper and accepted by himself and his assigns.

SHIPPER PER _____	CARRIER Q-3 NUREG - 1556, Vol. 5
---------------------------------	-------------------------------------------------

Part 3: Irradiators Built Before 1966

Before the adoption of the requirements of **10 CFR Part 71** in 1966, irradiators could be transported without being evaluated under the hypothetical accident conditions now incorporated in **10 CFR Part 71**. Unlike most post-1966 irradiators, pre-1966 irradiations are not certified shipping packages. Transport of pre-1966 units may require transferring the sealed source from the irradiator to a Type B package or use of a certified package for the irradiator containing the sealed sources.

VDH will consider a licensee's request for an exemption for a one-time shipment from **12VAC5-481-3130** only if these options are not viable.

An exemption may be granted if the request is authorized by law and will not endanger life or property or the common defense and security. In this case, an exemption request should demonstrate the need for the exemption, describe why alternatives considered are not viable, specify from what requirement(s) an exemption is requested and the period for which the exemption is requested, and describe steps taken to ensure that the shipment will not endanger life or property or the common defense and security (e.g., steps to minimize accident risk and to respond to a transportation accident). Typically, approved requests are for a limited period (e.g., 30 days).

Circumstances vary, but additional information supporting an exemption request may include the following:

- Manufacturer's (or distributor's) name and model number of the irradiator, the type and activity of radioactive material to be transported, and brief description of proposed trip (starting and ending points and approximate distance)
- Engineering drawings of irradiator
- Consideration of the following:
 - DOT's hazardous material routing requirements
 - Transport during time of low road usage
 - Use of good roads and avoidance of residential areas to maximum extent possible
 - Accompaniment of shipment by escort knowledgeable in the use of radiation survey instruments
 - Provision of escort with appropriate survey instruments and supplies to permit the establishment of a radiation exclusion area
 - Written procedures to be followed by the escort in an emergency situation.
 - Use of exclusive-use vehicle and shoring to limit movement of package during transport
 - Notification of state radiological health officials and local fire department of time and route of shipment.
- Planned date of shipment

Before applying to VDH for its approval, the licensee should contact other states radiological organizations within each state through which the shipment will be made to confirm the points of contact and to discuss the proposed controls for the shipment.

VDH reserves the right to accompany a shipment of an irradiator.

The agency must review these requests, which are typically requests to amend materials (**12VAC5-481 ‘Virginia Radiation Protection Regulations’**) licenses. Licensees should address their requests to:

Virginia Department of Health
Radioactive Materials Program
109 Governor Street, Room 730
Richmond, VA 23219

In addition to a VDH exemption, the licensee may also need a DOT exemption; contact DOT's Office of Hazardous Materials Technology at 202-366-4545 for additional information.

The response from the licensee for the exemption must demonstrate that the request is authorized by law and will protect public health and safety. It must also include the following information:

- Establish that the irradiator was built before 1966.
- Explain why an approved package cannot be used, the alternatives considered, and why each is not viable.
- Specify from what requirement(s) an exemption is requested and the period for which the exemption is requested.
- Describe procedures, controls, and other actions to be taken to ensure that the shipment will not endanger life or property or the common defense and security.

Reference: The names, addresses, and telephone numbers for officials in Agreement and Non-Agreement States are available on the NRC's 'Federal and State Material and Environmental Management' web page at <http://www.nrc-stp.ornl.gov/>. As an alternative, contact VDH at (804) 864-8150, during office hours.

Hazard Communications for Class 7 (Radioactive) Materials

Labeling Packages (49 CFR 172.400-450)

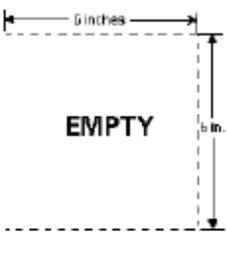
NOTE: IAEA, ICAO, and IMO may require additional hazard communication information for international shipments. This table must not be used as a substitute for the DOT and NRC regulations on the transportation of radioactive materials.

Placement of Radioactive Labels

! Labeling is required to be: (1) placed **near the required marking** of the proper shipping name, (2) printed or affixed to the package surface (not the bottom), (3) in **contrast** with its background, (4) **unobscured** by markings or attachments, (5) within color, design, and size tolerance, and (6) **representative** of the HAZMAT contents of the package

! For labeling of radioactive materials packages, **two labels** are required on **opposite sides** excluding the bottom

Determination of Required Label

<p>Size:</p> <p>Sides: > 100 mm (3.9 in.)</p> <p>Border: 5-6.3 mm (0.2-0.25 in.)</p>	 <p>49 CFR 172.436</p>	 <p>49 CFR 172.438</p>	 <p>49 CFR 172.440</p>	 <p>49 CFR 172.450</p>
Label	WHITE-I	YELLOW-II	YELLOW-III	EMPTY LABEL
Required when:	Surface radiation level < 0.005 Mew/hr (0.5 mem./hr)	0.005 Mew/hr (0.5 mem./hr) < surface radiation level ≤ 0.5 Mew/hr (50 mem./hr)	0.5 Mew/hr (50 mem./hr) < surface radiation level < 2 Mew/hr (200 mem./h) [Note: 10 Mew/hr (1000 mem./hr) for exclusive-use closed vehicle (§173.441(b))]	The EMPTY label is required for shipments of empty Class 7 (radioactive) packages made pursuant to §173.428. It must cover any previous labels, or they must be removed or obliterated.
Or:	TI = 0 [1 meter dose rate < 0.0005 Mew/hr (0.05 mem./hr)]	TI ≤ 1 [1 meter dose rate < 0.01 Mew/hr (1 mem./hr)]	TI ≤ 10 [1 meter dose rate < 0.1 Mew/hr (10 mem./hr)] [Note: There is no package TI limit for exclusive-use]	
Notes:	<p>! Any package containing a Highway Route Controlled Quantity (HRCQ) must bear YELLOW-III label</p> <p>! Although radiation level transport indices (TIs) are shown above, for fissile material, the TI is typically determined on the basis of criticality control</p>			

Content on Radioactive Labels

- ! RADIOACTIVE Label must contain (entered using a durable, weather-resistant means):
- (1) The **radionuclides** in the package (with consideration of available space). Symbols (e.g., Co-60) are acceptable
 - (2) The **activity** in SI units (e.g., Bq, TBq), or both SI units with customary units (e.g., Ci, mCi) in parenthesis. However, for domestic shipments, the activity may be expressed in terms of customary units only, until 4/1/97.
 - (3) The **Transport Index (TI)** in the supplied box. The TI is entered *only* on YELLOW-II and YELLOW-III labels

Some Special Considerations/Exceptions for Labeling Requirements

- ! For materials meeting the definition of another hazard class, labels for each secondary hazard class need to be affixed to the package. The subsidiary label may not be required on opposite sides and must not display the hazard class number
- ! Radioactive Material, excepted packages, under UN2910 (e.g., Limited Quantity, Empty packages, and Radioactive Instrument and Article), are exempted from labeling. However, if the excepted quantity meets the definition for another hazard class, it is re-classified for that hazard. Hazard communication requirements for the other class are required
- ! Labeling exceptions exist for shipment of LSA or SCO required by § 173.427 to be consigned as exclusive use
- ! The "Cargo Aircraft Only" label is typically required for radioactive materials packages shipped by air (§ 172.402(c))

Appendix R

12VAC5-481-451: Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material; and 12VAC5-481-1151: Reporting of Transaction Involving Nationally Tracked Sources

12VAC5-481-451

This appendix provides guidance to a licensee or applicant for the implementation of **12VAC5-481-451**, “Physical Protection of Category 1 and Category 2 Quantities of Radioactive Material.”

12VAC5-481-451 was revised in order to make it compatible with NRC regulation of 10 CFR Part 37. NRC revised 10 CFR Part 37 in March 2013 and the Agreement States were required to implement compatible regulations by March of 2016.

12VAC5-481-451 became effective on March 8, 2016. New definitions such as reviewing official, security zone, safe haven, telemetric position monitoring system, movement control center, etc., are included in the revised regulation. The requirements under this regulation provide reasonable assurance of the security of category 1 or category 2 quantities of radioactive material by protecting these materials from theft or diversion.

The table below lists the Category 1 and Category 2 quantities of radioactive materials:

Radionuclide			Category 1 (TBq) ^{1,2}	Category 1 (Ci) ^{1,2}	Category 2 (TBq) ^{1,2}	Category 2 (Ci) ^{1,2}
Am-241			60	1,620	0.6	16.2
Am-241/Be			60	1,620	0.6	16.2
Cf-252			20	540	0.2	5.4
Cm-244			50	1,350	0.5	13.5
Co-60			30	810	0.3	8.1
Cs-137			100	2,700	1	27
Gd-153			1,000	27,000	10	270
Ir-192			80	2,160	0.8	21.6
Pm-147			40,000	1,080,000	400	10,800
Pu-238			60	1,620	0.6	16.2
Pu-239/Be			60	1,620	0.6	16.2
Ra-226			40	1,080	0.4	10.8
Se-75			200	5,400	2	54
Sr-90 (Y-90)			1,000	27,000	10	270
Tm-170			20,000	540,000	200	5,400
Yb-169			300	8,100	3	81
Combinations of radioactive materials listed above ³					See footnote ⁴ below	

¹The aggregate activity of multiple, collocated sources of the same radionuclides should be included when the total activity equals or exceeds the Category 1 or Category 2 threshold.

²The primary values used for compliance are TBq. The curie (Ci) values are rounded to two significant figures for informational purposes only.

³Radioactive materials are to be considered aggregated or collocated if breaching a common physical barrier (e.g., a locked door at the entrance to a storage room) would allow access to the radioactive material or devices containing the radioactive material.

⁴If several radionuclides are aggregated, the sum of the ratios of the activity of each source, i of radionuclide, n , $A(i,n)$, to the Category 1 or Category 2 threshold for radionuclide n , Q_n , listed for that radionuclide equals or exceeds one. [(aggregated source activity for radionuclide A) / (quantities of concern for radionuclide A)] + [(aggregated source activity for radionuclide B) / (quantities of concern for radionuclide B)] + etc.... ≥ 1

12VAC5-481-451 has the following four main Subsections:

Subsection A, requires licensee to establish a physical protection program.

Subsection B, requires licensees to establish background investigation and an access authorization program to ensure that individuals who have unescorted access to Category 1 and 2 quantities of radioactive material and reviewing officials are trustworthy and reliable.

Subsection C, requires licensees to establish, implement, and maintain a security program that is designed to monitor and, without delay, detect, assess, and respond to any actual or attempted unauthorized access to Category 1 or Category 2 quantities of radioactive material in use or storage.

Subsection D, requires licensees to provide for physical protection of Category 1 or Category 2 quantity of radioactive materials in transit. These requirements apply to a person delivering material to a carrier for transport, as well as cases in which the person transports material. If licensees intend to transfer category 1 or category 2 quantities of radioactive material to a licensee of the agency, the NRC, or another agreement state, then prior to conducting such transfer they are required to verify with the NRC's license verification system or the license-issuing authority that the transferee's license authorizes the receipt of the type, form, and quantity of radioactive material to be transferred.

NRC Guidance Documents

Licensees or applicants should refer to NRC NUREG 2155 and NUREG 2166 for detailed guidance in implementing the physical protection requirements set forth under 12VAc5-481-451.

NUREG 2155 and NUREG 2166 are found in the following link:
<http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/>

12VAC5-481-1151: Reports of Transactions Involving Nationally Tracked Sources

Nationally tracked source is a sealed source containing a quantity equal to or greater than category 1 or category 2 levels of any radioactive materials listed in **12VAC5-481-3780**. If licensees possess, ship, or receive quantities of material exceeding Category 1 or category 2, then they must also comply with requirements specific to Category 1 or category 2 quantities.

The regulations in **12VAC5-481-1151** require that each licensee that manufactures, transfers, receives, disassembles, or disposes of a nationally tracked source shall complete and submit an NSTS report